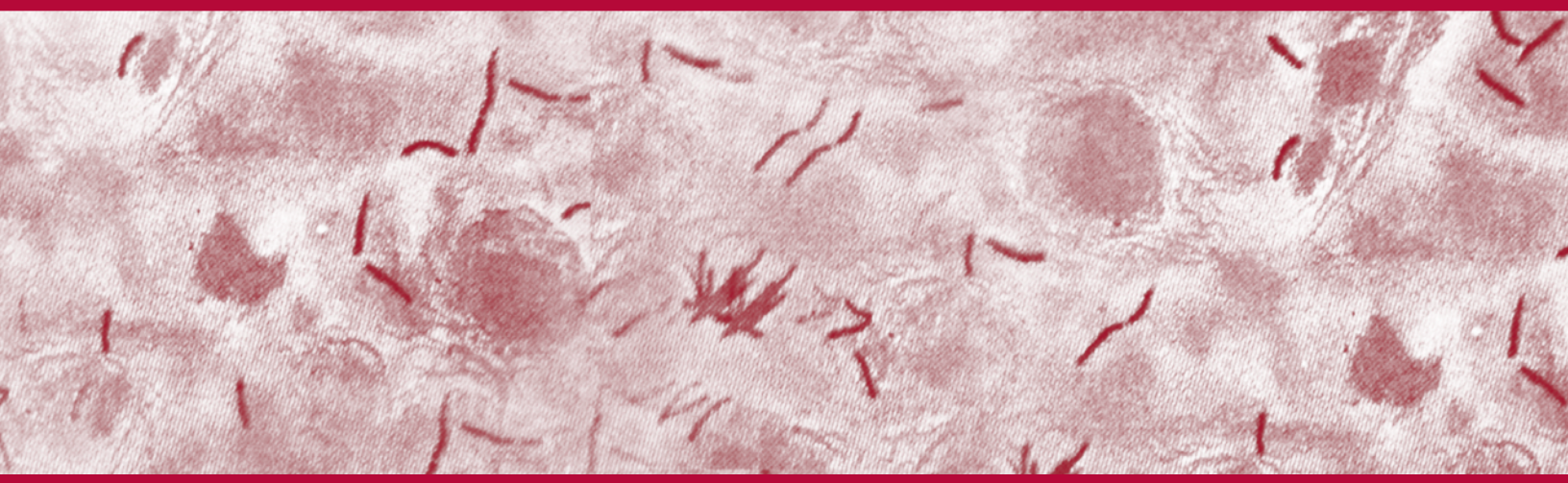
# Compendium of Indicators for Monitoring and Evaluating National Tuberculosis Programs

WHO/HTM/TB/2004.344



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## ACRONYMS AND ABBREVIATIONS

| | |
|---|---|
| AFB | Acid-Fast Bacilli |
| AIDS | Acquired Immunodeficiency Syndrome |
| BMU | Basic Management Unit |
| DHS | Demographic and Health Survey |
| D.O.T. | Direct Observation of Therapy |
| DOTS | The internationally recommended strategy for the control of tuberculosis |
| DRA | Drug Registration Authority |
| DRS | Drug Resistance Surveillance |
| FM | Fluorescence Microscopy |
| GFATM | Global Fund to Fight AIDS, TB, and Malaria |
| GLP | Good Laboratory Practices |
| GMP | Good Manufacturing Practices |
| HIV | Human Immunodeficiency Virus |
| HR | Human Resource |
| IEC | Information, Education, and Communication |
| INN | International Nonproprietary Name |
| M&E | Monitoring and Evaluation |
| MDP | Medium-term Development Plan for tuberculosis control |
| MDR-TB | Multidrug-Resistant Tuberculosis |
| MOH | Ministry of Health |
| NACP | National AIDS Control Program |
| NGO | Nongovernmental Organization |
| NTP | National Tuberculosis Control Program |
| PHC | Primary Health Care |
| PLWHA | People Living With HIV/AIDS |
| QA | Quality Assurance |
| TB | Tuberculosis |
| TMU | Tuberculosis Microscopy Unit |
| UN | United Nations |
| UNION | International Union Against Tuberculosis and Lung Disease |
| USAID | United States Agency for International Development |
| VCT | Voluntary Counseling and Testing |
| WHO | World Health Organization |

# INTRODUCTION

The World Health Organization (WHO) declared tuberculosis (TB) a global emergency in 1993, in response to a steady increase in the incidence of TB, shifting dynamics in TB disease related to the human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) epidemic, and the emergence of multidrug-resistant TB (MDR-TB). The increasing burden of TB is due to many factors, including neglect of TB control by governments; poor management of programs; the spread of HIV; poverty; population growth; and rapid, uncontrolled urbanization. In response, a cost-effective and efficient strategy, known as DOTS (the internationally recommended TB control strategy), was developed. The DOTS strategy is designed to correct weaknesses in previous models of program management and to strengthen diagnosis and treatment services. Key components of the DOTS strategy include:

1. Sustained political commitment
2. Access to quality-assured TB sputum microscopy
3. Standardized short-course chemotherapy to all cases of TB under proper case management conditions, including direct observation of treatment
4. Uninterrupted supply of quality-assured drugs
5. Recording and reporting system enabling outcome assessment.

Although some progress has been made, persistent gaps remain in coverage, case detection, and treatment success—three key global indicators recommended by the World Health Assembly for measuring national TB control program (NTP) success.

The World Health Assembly recommended that each national TB program achieve a case detection rate of 70% and a treatment success rate of 85% by 2005 in order to bring the worldwide epidemic of TB under control by treating active cases and reducing transmission.

Today, nearly one-third of the global population is infected with *Mycobacterium tuberculosis* and at risk of developing the active disease. Almost 9 million people develop active TB every year, and about 2 million die from the disease.[1] The poor and marginalized in the developing world are at greatest risk: 95% of all cases and 98% of deaths due to TB occur in resource-poor countries.[2] Although many of the national DOTS

[1] *A guide to monitoring and evaluation for collaborative TB/HIV activities.* Field test version. Geneva, World Health Organization, 2004 (WHO/HTM/TB/2004.342, WHO/HIV/2004.09).
[2] Dye C et al. Global burden of tuberculosis: estimated incidence, prevalence and mortality by country. *Journal of the American Medical Association*, 1999, 282:677–686.

programs are doing well in at least one of the key indicators mentioned above, there are very few countries succeeding in all three.

TB control programs face many new and existing challenges. Traditionally, a lack of political commitment to TB control, which in turn leads to weak support of TB control activities from the health system and society, continues to be an ongoing challenge in many countries. Similarly, weak public sector health services, which desperately need to enhance their capacity to implement, expand, and sustain DOTS-based services without compromising the quality of case detection and treatment, hinder progress in TB control.

Among the newer challenges, the impact of the HIV/AIDS epidemic on TB incidence is daunting. Even in the presence of well-functioning TB control programs, the incidence of active disease is increasing in settings with a high prevalence of HIV. The increasing impact of HIV on the incidence of TB disease, particularly in sub-Saharan Africa, necessitates new partnerships and approaches. Therefore, both TB and HIV programs need to develop and implement collaborative interventions to effectively cope with the impact of coinfection.[3]

Another challenge is the exponential increase in MDR-TB. This challenge requires effective implementation of the DOTS strategy to prevent new MDR-TB cases. Broadly speaking, sustained support for DOTS programs will facilitate their integration into the primary health care system and adaptation to reforms within the health sector.

In 2002, WHO and partner organizations expanded the DOTS strategy to address the challenges mentioned above. The expanded framework reinforces the five essential elements of DOTS and emphasizes the importance of programs that address TB and HIV coinfection, MDR-TB, and other areas. The expanded strategy places equal emphasis on the technical, managerial, social, and political dimensions of DOTS. It also underscores the contribution that TB control makes to poverty alleviation by reducing the socioeconomic burden of the disease. This expanded DOTS strategy includes the following key operations:[4]

1. Establish a national tuberculosis program with a strong central unit

2. Prepare a program development plan and a program manual, and establish the recording and reporting system allowing cohort analysis of treatment outcomes

[3] *TB/HIV—a clinical manual*. Geneva, World Health Organization, 1996 (WHO/TB/96.200).
[4] *Treatment of tuberculosis: guidelines for national programs*. Geneva, World Health Organization, 2003 (WHO/CDS/TB/2003.313).

3. Plan and initiate a training program

4. Set up a microscopy services network in close contact with primary health care (PHC) services and subject to regular quality control to ensure that detection and cure of smear-positive TB cases remain a priority, through effective decentralization of diagnosis

5. Organize treatment services within the PHC system where directly observed short-course chemotherapy is given priority

6. Secure a regular supply of drugs and diagnostic material

7. Design and implement a plan of supervision of key operations at the intermediate and district levels.

An important feature of the expanded framework is that it broadens the scope of monitoring and evaluation (M&E) of TB activities to include both traditional program outcome indicators, such as case detection and treatment success rates, and indicators that measure the technical, managerial, social, and political dimensions of DOTS. Consequently, the expanded framework demonstrates why it is necessary to routinely collect information on a standard set of programmatic inputs, processes, and outcomes to better identify strengths and weaknesses and track progress.

## Objectives of the Compendium

TB control has been one of the leading fields to routinely collect information that measures the most critical output and outcome indicators used for national and global reporting. TB programs in the vast majority of countries are currently using these indicators for M&E for TB control at the national and local levels. Still, there is some variability in the definitions of core indicators, and guidance is needed on additional indicators that are critical for M&E of the rapid scale-up of TB programs.

The overall objective of this compendium is to encourage and facilitate internal and external M&E of TB control programs to improve quality and effectiveness. This compendium provides a comprehensive and standardized listing of the most widely used indicators relevant to developing countries, and it strives to achieve uniformity in defining indicators to allow comparisons over time and between different programs. The compendium draws on numerous important, previously established guidelines from WHO and the International Union Against Tuberculosis and Lung Disease (UNION) on the selection and use of indicators. Although WHO and the UNION have

been using a range of process indicators for a long time, a few process-level indicators presented in this compendium have been adapted from related fields.

The specific objectives of the compendium are to:

- Provide standardized M&E terminology across indicators and TB control programs
- Encourage consistent use of indicators to monitor and evaluate programs
- Provide guidance for the development of comprehensive evaluation plans, including selection of indicators to measure progress in specific areas
- Serve as a resource for the different components of the M&E process.

## Intended Audience

This compendium is designed for health professionals with varied levels of training and experience in M&E. Several different audiences should find this compendium relevant to their activities, including:

- Directors, managers, and technical staff of TB programs worldwide
- International partners and consultants responsible for designing and evaluating collaborative TB control projects with host country institutions
- In-country evaluation specialists responsible for monitoring performance and for evaluating the effectiveness of health systems, including TB programs
- Health system planners.

## Organization of the Compendium

This compendium provides a detailed review of M&E for national TB programs and indicators for measuring DOTS implementation and expansion. The review includes information on M&E for TB control programs, sources of data, and effective use of M&E data for program improvement and advocacy. The indicators in this document are divided into three sections—global outcome indicators, routinely reported program outcomes, and indicators for measuring implementation of DOTS components. The indicators for measuring the implementation of DOTS correspond to the five components of the DOTS strategy—political commitment, smear microscopy for diagnosis, directly observed short-course chemotherapy, reliable drug supply, and recording and reporting. This section also includes indicators for tracking the progress

of activities related to program supervision, human resources development, and health systems.

A supplement to this compendium will present indicators for M&E of specific programmatic approaches, such as TB and HIV integration, MDR-TB, public and private mix, community-based DOTS, TB control in prisons, health systems capacity, and social mobilization and IEC (information, education, and communication).

# I. DEFINING MONITORING AND EVALUATION

## What Is Monitoring and Evaluation?

M&E is the collective use of social science and epidemiological research methods to assess, and eventually improve, the implementation of programs, or components of programs.[5] The overall purpose of M&E is to measure program effectiveness, identify problem areas, gather lessons learned, and improve overall performance. M&E activities are used to assess progress towards specific objectives and address weaknesses in program design. A number of different methods or approaches are available for tracking changes and measuring program performance: monitoring, evaluation (i.e., process, outcome, and impact), and surveillance.

***Monitoring*** is the routine tracking of programs using input, process, and outcome data that are collected on a regular, ongoing basis. Monitoring is used to assess whether or not planned activities are carried out according to schedule. Monitoring activities reveal the extent to which the program is progressing towards identified targets and services are being utilized. An abrupt or unexpected change in monitoring data may trigger the need for a more formal evaluation of the activities.

***Process evaluation*** is used to measure the quality and integrity of program implementation and to assess coverage. It may also measure the extent to which the intended target population uses services. The results of process evaluations are intended to inform midcourse corrections in the program to improve program effectiveness.

***Outcome and impact evaluations*** measure program results and the effect on the target population. Outcome evaluations measure the extent to which stated objectives are achieved with respect to the program's goals. They are used to assess the influence of program activities by measuring changes in knowledge, attitudes, behaviors, skills, community norms, utilization of health services, and health status at the population level. An impact evaluation is a very specific type of evaluation design that determines how much of the observed change in outcomes can be attributed to specific program efforts. Impact evaluations are carried out following specific scientific designs and involve complex data collection and analysis procedures. They are not undertaken routinely and are usually reserved for specific situations, such as determining the success of a project for scale-up or replication.

[5] Rossi P, Freeman H. *Evaluation: a systematic approach*. Newbury Park, CA, Sage Publications, 1993.

***Surveillance*** is the routine collection of epidemiological data (i.e., disease outcomes) to track trends in disease incidence or prevalence over time. Data may be collected through seroprevalence surveys or through the routine reporting of cases seen by health facilities. Some surveillance activities also collect basic demographic and related data along with disease status. Surveillance data are usually collected at the health facility or community level and aggregated through the administrative units to arrive at national or subnational estimates. Although surveillance data are an important source for M&E, this should not be confused with, or substituted for, actual program monitoring. Surveillance data provide outcome-level information on disease status, but little or no information on program activities. Surveillance data must be linked with other sources of programmatic data in a monitoring system.

## Why Is Monitoring and Evaluation Important?

M&E plays an important role in the day-to-day management of health programs and provides program managers with the information and insight needed for strategic planning, program design and implementation, and informed decision-making about human and financial resources, especially in resource-limited settings. The evaluation component of M&E allows more extensive analysis of program data. Evaluations can determine whether a program is on track to meet stated objectives and, if not, what midcourse corrections might be necessary.[6] A well-designed evaluation can also assess the extent to which the program achieved the desired impact on the target population. Program monitoring and impact evaluation are complementary activities that allow program managers to measure coverage of their target populations to identify gaps and underserved populations.

## What Are the Characteristics of a Good Monitoring and Evaluation System?

A good M&E system serves several functions. Within the program or project, the M&E system is structured to ensure the most efficient use of resources to generate the data needed for decision-making. It guides data collection and analysis to increase consistency and to enable managers to track trends over time. It should serve many constituencies, including program managers, donors, and government planners, but at the same time bring all of the various interests together into one system to avoid duplication of efforts. A good M&E system should serve as a catalyst to coordination.

[6] See note 5 above.

An M&E system includes a number of components.[7] First, the M&E unit itself is a functional unit or group within the program that is in charge of M&E activities. Next, the system should be based on a strategy that includes clear goals and targets, guidelines for the implementation of activities, and specific indicators by which to measure program progress. Finally, the M&E system should also include plans for data collection, analysis, and dissemination of results. Appendix A provides a checklist of features of a good M&E system.

## How Do You Select a Good Indicator?

An indicator is a specific measure of program performance that is tracked over time by the monitoring system. Indicators should reflect the stated goals of the program, allowing managers to track distinct progress towards benchmarks. Indicators should measure the overall scope of the program objectives, including the dimensions of quantity, quality, and cost. Indicators covering quantity are usually fairly easy to develop and include elements of program performance, such as logistics and supplies, number of staff and activities, and program coverage. Likewise, cost elements are relatively easy to incorporate into an M&E system through existing budget and allocation processes (although M&E planners frequently overlook this element). The qualitative aspects of programs are harder to measure but should be incorporated nonetheless. Indicators of quality cover program elements, such as competency of providers, adherence to standards, and quality of care issues. A thorough M&E plan will incorporate all of these elements into its selection of indicators.

The selection of indicators usually takes place during the process of program planning and/or replanning, preferably with the participation of the implementing agency and key stakeholders. It requires careful foresight and practical consideration. If the objectives are clear, then selecting appropriate indicators to measure program performance can be relatively straightforward. Table 1 lists standard selection criteria for judging the relevance of specific indicators.

[7] *National AIDS programme: A guide to monitoring and evaluation*. Geneva, Joint United Nations Programme on HIV/AIDS (UNAIDS), 2000 (UNAIDS/00.17E).

**Table 1. Criteria for Indicator Selection**

| The following criteria are useful in helping to select indicators for program monitoring: | |
|---|---|
| Valid | Indicators should measure the condition or event they are intended to measure. |
| Reliable | Indicators should produce the same results when used more than once to measure the same condition or event, all things being equal (e.g., using the same methods, tools, or instruments). |
| Specific | Indicators should measure only the condition or event they are intended to measure. |
| Sensitive | Indicators should reflect changes in the state of the condition or event under observation. |
| Operational | Indicators should be measured with definitions that are developed and tested at the program level and with reference standards. |
| Affordable | The costs of measuring the indicators should be reasonable. |
| Feasible | It should be possible to carry out the proposed data collection. |
| Comparable | Indicators should be comparable (e.g., over time, across geographical lines). |

## Data Quality

An M&E system is only as good as the data that are collected. The data should be appropriate, complete, consistent, and timely. Many current efforts at data collection, particularly those conducted routinely, result in poor-quality data because of a lack of proper training and supervision. If the individuals recording the data are not using the data and do not fully appreciate data needs for program management beyond the facility level, the quality will most likely be poor. This in turn leads to declining use. One of the key functions of an M&E system is to oversee all data collection and ensure that data are appropriately used and the results are disseminated throughout the system, but especially to the collection level. Changes in health programs that are directly based on evidence from the field reinforce the efforts at the peripheral level to complete routine reporting. When health workers understand the importance of the data they are collecting, quality is likely to improve, building more confidence in and use of monitoring data.

# II. MONITORING AND EVALUATION FOR TUBERCULOSIS PROGRAMS

Like other health programs, TB programs have a unique set of challenges for M&E. First, the steps required to diagnose infectious TB are difficult to monitor. Simply ensuring that each TB case has submitted sputum smears for analysis and has received results often requires tedious review of laboratory registers. The lengthy treatment period, which involves several medications, is another aspect of the clinical management of TB that complicates M&E. Even though treatment adherence and other direct observation of therapy (D.O.T.) activities are difficult to verify and monitor, they are absolutely critical to curing the patient, preventing further transmission of TB, and preventing the emergence of drug-resistant bacteria.

M&E for TB programs is paramount to ongoing program planning and implementation. To further develop M&E standards for TB control, one must move beyond the widely used case detection and treatment outcome indicators and develop an M&E framework with a standardized set of input, process, output, and outcome indicators to measure DOTS implementation. Such indicators should be related to the key components and activities of the DOTS strategy.

There are substantial efforts under way in sector programming and health surveillance system development to improve cross-fertilization of the lessons learned in M&E processes and indicator prioritization and to integrate and/or coordinate tools and results across programs wherever possible. Given the need for focused attention and tracking of TB control efforts, with the worsening TB and HIV epidemics, there is strong support for TB-specific M&E indicators and TB control program M&E frameworks. Nonetheless, it is important to consider the efficient and effective use of TB indicators and data collection methods within the broader health framework and to build on cross-program synergies and expertise.

> The process of developing a framework helps generate a clear picture of goals and pragmatic objectives, as well as of the elements both within and external to project operations that will affect its success in the particular context.

## Monitoring and Evaluation Framework for Tuberculosis Programs

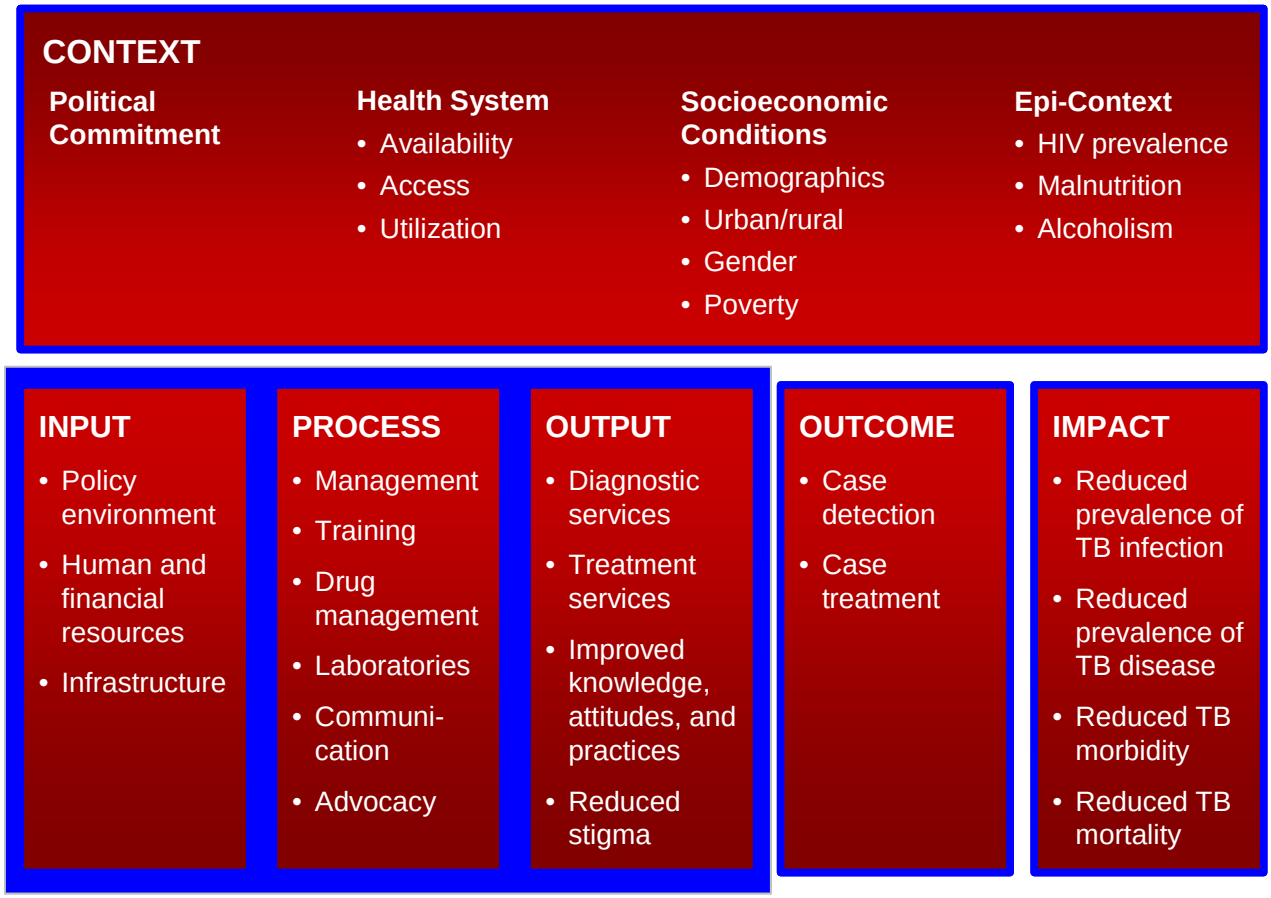
An M&E framework is a visual conceptualization of how the elements of a program fit together, that is, which inputs are necessary for the program's activities (process), what outputs are expected from the activities, and what short- and long-term outcomes will

ultimately result from the program.[8] A framework can be used as a tool to understand and analyze a program, which is crucial for developing and implementing sound M&E plans. Developing M&E frameworks also helps clearly define the relationships among key factors in project implementation and success. These factors include internal program components and external and contextual influences on the program. Designing a framework also deepens the understanding of managers, implementers, and other partners in many practical ways as well as provides a foundation for selecting appropriate and useful indicators.

Fig. 1 describes a basic M&E framework that could be adapted for many TB programs. Its components consist of boxes labeled from "input" to "impact." Each box represents a different level and section of a whole program. For example, at the input level, one might be concerned with measuring the human resources available to implement a particular diagnostic procedure or to maintain a set of patient records. At the outcome level, one is concerned with measuring some of the classic indicators of TB programs, such as the case detection or treatment rates. The ultimate desired outcome is lowered TB infection, which translates into lowered mortality and morbidity in a specific population. The challenge for any TB program is to demonstrate that inputs produce the desired impact (decreased mortality and morbidity related to TB), given the contextual factors and the process-level variables. However, linking inputs to impact is exceedingly complex, given the large variation in process- and output-level operations. The utility of an M&E framework is that it allows the evaluator to place program objectives in the context of a systematic framework for evaluation. Once a framework has been developed, the process of selecting indicators for a TB control program becomes more obvious.

[8] Bertrand J, Magnani R, Rutenberg N. *Evaluating family planning programs with adaptations for reproductive health*. Chapel Hill, NC, Carolina Population Center, 1996.

**Figure 1. M&E Framework for TB Control Programs**




The shaded area around the input, process, and output boxes illustrates how the elements within these components of the framework are flexible or interchangeable. For example, depending on what stage of implementation the TB program is functioning, a national TB policy may be an output at the early stages but may be an input once a program is fully functional.

Table 2 lays out basic M&E terminology as it has been applied in the framework and, more generally, in the social sciences and health care sectors.

**Table 2. Program Components: Input, Process, Output, Outcome, and Impact**

| Program Components | Definitions |
|---|---|
| Input | Human and financial resources, physical facilities, equipment, clinical guidelines, and operational policies that are the core ingredients of a program and enable delivery of health services. |
| Process | Refers to the multiple activities that are carried out to achieve the objectives of the program. It includes both what is done and how well it is done. For example, if the goal of the program is to train 100 service providers (output) in sputum smear microscopy, process-level indicators could include the development of a curriculum, the implementation of the training courses, and the quality of slides. |
| Output | The results of program-level efforts, such as the number of activities conducted in areas such as service delivery, including commodities and logistics, management and supervision, or training. Service delivery outputs may measure the volume of services provided to the target population, as well as the adequacy of the service delivery system in terms of access, quality of care, and program image/client satisfaction. In many cases, M&E is limited to outputs because these data are collected on a routine basis. |
| Outcome | Changes measured at the population level, some or all of which may be the result of a given program or intervention. Outcomes may refer to specific results—such as improvements in case detection and treatment success rates—that are clearly related to the program. |
| Impact | Program results achieved among the target population and to what extent these achievements can be attributed to the intervention (e.g., reducing morbidity and mortality as a direct result of introducing effective public–private partnerships). |

## Indicators for Tuberculosis Programs

One of the critical steps in designing and carrying out an evaluation of a TB program is the selection of appropriate indicators.[9] If the objectives of the program have been clearly stated and presented in terms that define quantity, quality, and time, selecting appropriate indicators to measure program success can be a relatively easy task. However, even when objectives are well articulated, the choice of indicators for the evaluation still requires careful thought and consideration of conceptual and pragmatic matters. The M&E framework will help to guide this process by defining activities at each level for which corresponding indicators are needed. A balance of input, process, output, and outcome indicators is necessary to explain success and gaps in program implementation. For example, if a TB control program has only one indicator, treatment success, it would be difficult to explain why that may be low. A program

[9] See note 8 above.

with a range of indicators from input to outcome could look further to see the quality of diagnostic services, determine whether staff had been trained in DOTS, or see whether D.O.T. was being implemented. These process and output indicators help to explain why treatment success may be low and therefore help to identify areas that need to be strengthened in order to improve treatment success.

## Data Sources

Once a TB program has designed and adopted an M&E framework and selected the appropriate indicators, data collection strategies need to be selected. There is a variety of methods typically used to gather TB information. No single data source can provide all of the information required for M&E—a combination is necessary:

### Routinely Collected Health Information

Routine data collection at TB treatment facilities and microscopy units is the most common way of collecting TB data for patient and treatment facility management, for monitoring resources used and services provided, and for disease surveillance. Data are recorded by the health staff at the facility or microscopy units while they perform their daily health care activities. These data are recorded on standard reporting forms, which are sent to basic management units (BMUs), where they are aggregated and sent to the national level. For example, routine data collected include service statistics, such as the number of cases registered by category and type of TB, the number of deaths, and the number cured. Some countries have a computerized routine health information system that facilitates analysis and reporting.

The district, regional, and national TB offices are responsible for their respective geographic areas. Monitoring is often required on a monthly or quarterly basis using several different data collection tools. Since the implementation of the DOTS strategy, WHO and partners have developed standardized reporting forms for evaluating treatment results and increasing treatment effectiveness and efficiency. The forms have been classified into five categories:

- Record forms at the health facility
- Record and report forms at the district level
- Record and report laboratory forms
- Report forms at the regional level
- Report forms at the national level.

Appendix B provides a brief description and example of key record and report forms at the health facility, district level, and laboratory.

**Box 1: Definitions for TB Diagnosis, Treatment, and Management Units**

The following terms are used throughout this document to refer to points of TB diagnosis, treatment, and/or management. TB treatment facilities and TB microscopy units exist within general integrated health service facilities and health management structures in the case of BMUs. These are not stand-alone or vertical TB facilities or units but have been given a specific name to help describe their nature and function in terms of TB control programs.

**Basic Management Unit**
A BMU is defined in terms of management, supervision, and monitoring responsibility. A unit for TB control may have several treatment facilities, one or more laboratories, and one or more hospitals. The defining aspect is the presence of a manager or coordinator who oversees TB control activities for the unit and who maintains a master register of all TB patients being treated, which is used to monitor the program and report on indicators to higher levels. Typically, the units correspond to the government's second subnational administrative division, which might be called, for example, a "district," "county," or "rayon." The TB control program may choose to lump or split these divisions to form operational units that are manageable (in terms of the population served, the geographic area covered, and the laboratory services available). It is internationally recommended that a BMU cover a population between 50,000 and 150,000 or up to 300,000 for large cities.

A BMU is implementing the DOTS strategy when all components of the internationally recommended approach to TB control are in place. These include political commitment; uninterrupted drug supply; use of smear microscopy in diagnosing TB cases; standardized short-course treatment regimens; direct observation of treatment, at least during the initial phase of treatment and during any phase that includes rifampicin in the treatment regimen; and monitoring of treatment outcomes for 100% of patients with TB.

**TB Treatment Facility**
A TB treatment facility is defined as a facility that provides standardized short-course treatment regimens for TB patients. A DOTS treatment facility includes all components of the internationally recommended approach to TB control, including standardized short-course treatment regimens; direct observation of treatment, at least during the initial phase of treatment and during any phase that includes rifampicin in the treatment regimen; and monitoring of treatment outcomes for 100% of patients with TB.

**TB Microscopy Unit**
A TB microscopy unit (TMU) is defined as a unit where sputum smear microscopy is performed. This unit should have adequate supplies and trained staff to perform the proper functions for diagnosis. It is internationally recommended that a TMU cover a population between 50,000 and 150,000. In most settings, this results in workloads within the recommended rage of 2 to 20 smears per day.

## Global TB Reporting

Data are collected from national program managers and are analyzed by WHO's Global TB Monitoring and Surveillance Project, in close collaboration with the DOTS Expansion Working Group of the Stop TB Partnership, to chart progress in TB control and implementation of the DOTS strategy for each country. The WHO global report is produced each year and includes data on estimated incidence, case notifications, and treatment outcomes from all national control programs that have reported to WHO, together with an analysis of plans, finances, and constraints on DOTS expansion for 22 high-burden countries. WHO's request for results on these indicators enables global TB surveillance and intercountry comparisons. However, indicators used at this global level are first and foremost seen as critical to understanding the progress made towards

TB control at the national and local levels and should be used for monitoring, evaluation, and problem-solving at all levels.

### Special Surveys or Studies

Special surveys or studies may be needed to determine many of the epidemiological and behavioral indicators that are not collected through monitoring or evaluation. Such studies are often more comprehensive than standard collection, but at the same time, they are more costly and require a specific technical capacity for implementation. These factors limit the number of special studies that are conducted. Examples of special surveys include the following:

- ***TB prevalence surveys*** provide information about the size of the TB problem in the general population; even more important, if the surveys are conducted periodically, they provide information on the problem's trend over time. This is important for evaluating whether TB control efforts reduce the TB problem. A TB prevalence survey is similar in methodology to any population-based survey. A representative sample of the general population is selected and then screened to identify suspects: complaints of cough for at least 2 or 3 weeks and/or, if appropriate, X-ray. A positive sputum smear and/or a positive culture provide proof of TB disease. Information on this type of survey is available in work by Shimao[10] and Tupasi and others.[11]

- ***Serological surveys*** determine the level and trend of HIV infection in TB using representative samples of new cases. WHO has developed a method for conducting these surveys. Information on this type of survey is available in the Zambia Demographic and Health Survey[12] and in guidelines published by WHO.[13]

- ***Population-based surveys*** provide valuable information on knowledge of TB signs and treatment, attitudes towards TB patients, and health-seeking behaviors from representative samples of the community. Demographic and Health Survey (DHS) and the Living Standard Measurements Survey are two widely used population-

[10] Shimao T. Tuberculosis prevalence surveys. *Bulletin of the International Union Against Tuberculosis*, 1982, 57:126–132.
[11] Tupasi T et al. The 1997 Nationwide Tuberculosis Prevalence Survey in the Philippines. *International Journal of Tuberculosis and Lung Disease*, 1999, 3(6):471–477.
[12] *Zambia demographic and health survey 2001–2002*. Calverton, MD, Central Statistical Office [Zambia], Central Board of Health [Zambia], ORC Macro.
[13] World Health Organization, Centers for Disease Control and Prevention, Joint United Nations Programme on HIV/AIDS. *Guidelines for conducting HIV sentinel serosurveys among pregnant women and other groups*. Geneva, UNAIDS/WHO Working Group on Global HIV/AIDS and STI Surveillance, 2003.

based surveys. DHS surveys are now beginning to test the use of TB-specific questions both in the standard questionnaires and in a specific TB module.

- ***Vital registration surveys*** are used to measure annual TB mortality rate. This method is only possible when the death registry is of a known geographic coverage and quality. Special studies can then be undertaken with samples of deaths attributed to TB to determine the medical bases for the diagnosis and the reliability of the death registry regarding the reported cause of death. The mortality rates should be analyzed according to category of disease (e.g., pulmonary, meningitis, other extrapulmonary), associated conditions (e.g., AIDS, diabetes, alcoholism), age, sex, and geographical region.

- ***Tuberculin surveys*** provide a measure in children of the prevalence of infection, from which the risk of infection can be estimated. The sample should be representative of the child population. WHO, the Tuberculosis Surveillance and Research Unit in the Netherlands, and the UNION have developed the methodology for conducting tuberculin surveys and interpreting results.[14]

- ***Drug resistance surveillance (DRS)*** provides information on the prevalence of anti-TB drug resistance among new and previously treated TB cases. WHO and the UNION have developed the methodology for these DRS surveys.[15]

- ***Health facility surveys*** have the prime objective of describing the availability, functioning, and quality of TB activities and services at all levels of the health system and laboratories. Data are also collected to measure the availability of anti-TB drugs, as well as supplies and equipment. This information can be obtained by interviewing informed respondents at the facility and observing its operations.

## Developing a Monitoring and Evaluation Plan for Tuberculosis

Planning for M&E is crucial. M&E activities themselves require allocation of program resources, such as time, money, and personnel, so these items must be intrinsically built into a program's budget. Only well-planned M&E will generate strong empirical evidence showing that the activities of the project have indeed had demonstrable effects on the desired goals. Planning is required to develop valid indicators that will be

[14] Arnadottir T et al. Guidelines for conducting tuberculin skin test surveys in high prevalence countries. *Tubercle and Lung Disease*, 1996, 77(Suppl. 1):1–19.
[15] Aziz MA et al., eds. *Guidelines for surveillance of drug resistance in tuberculosis*. Geneva, World Health Organization, 2003 (WHO/CDS/TB/2003.320).

backed up by reliable data. M&E planning must also ensure that the information gathered is fed back into subsequent decisions concerning program implementation.

Countries that have already developed a medium-term development plan (MDP) or 5-year implementation strategy can use this plan as a basis for their M&E plan. Most MDPs have already defined the goals and objectives of the TB program and strategies for program implementation. M&E plans can be organized in many ways. There are a number of important elements that need to be included for a plan to be considered complete:

1. An explicit statement of the assumptions being made about the context of the program and a clear expression of the overarching goals and objectives being sought.

2. An implementation strategy describing how planned activities will take place, including person(s) responsible, budget allocations, tools to be used for data collection, a plan to ensure the quality of data collection, and capacity building plans.

3. An explicit description of the important relationships or interactions that are expected to occur among program activities, targets, and outcomes, including a plan to foster these links for appropriate use of data.

4. Well-defined indicators along with the exact ways they will be measured and calculated (both the numerator and denominator). The set of indicators should be discussed in detail, including baseline values, data collection, schedules, data sources, and estimated resources needed for associated M&E activities.

5. An outline of the partnerships and other organizations that will be involved in each activity, and how they will be involved in M&E as data providers and users.

6. Discussion for using M&E results, including methods of dissemination, target audiences, dissemination calendars, and appropriate medium for presenting results.

A complete M&E plan covers the full range of the intervention, from the most basic assumptions through the logic of implementing activities, the technical details of data collection, indicator calculation, and analysis and use of data in order to create a coherent and useful system that ultimately will improve program performance.

## Using Monitoring and Evaluation Results

The ultimate purpose of collecting TB data is for their use in policy formulation, program planning, and M&E. M&E results should be analyzed and disseminated to others in a format that is both understandable and usable. There are three critical questions that should be answered when considering data analysis, use, and dissemination:

1. Who are the potential audiences or users of the results?

2. Which particular finding will be of most interest to each potential audience or user?

3. What are the best media channels to reach each potential audience or user?

### Data Analysis

The analysis of indicators should be based on previously discussed factors, such as the target population (e.g., homeless, prisoners, general population), geographical area, or age. Data analysis involves quantitative manipulation of the information collected. This manipulation, or analysis, of information may be possible by hand or by a computerized database, depending on the resources available and the amount of information being processed.

The analysis of indicators may involve stratifying results to identify outliers in performance among operational units, looking at the results in the context of other indicators, asking questions about the possible factors contributing to the result, and perhaps seeking additional data.[16] For example, a generally high treatment success rate nationally may obscure the fact that some units are not performing well. Furthermore, a generally high treatment success rate may seem at odds with the finding of a high proportion of retreatment cases among the total cases registered; this may lead to suspicion about the appropriateness of case classification, but the paradox may also be resolved if most of these retreatment cases had previous treatment outside the program (in private practice). Ultimately, the exploration may involve a review of TB registers and/or a retrospective interview with retreatment cases to collect information that is not recorded in the register.

[16] See note 8 above.

## Data Use

Indicators and monitoring systems are worthwhile only if they are used. Too often, data are collected but never analyzed, or data are analyzed but never used to improve or modify existing practices or policy. The indicators derived from this compendium can be used to monitor the progress in implementing the various elements of the NTP. Are the basic structures in place, and are they functioning adequately? Which components are performing well, and which ones are not? If the indicators are collected regularly over time, then it becomes possible to determine whether particular components have improved or declined in performance.

**Reasons for Sharing M&E Results**

- Improve performance and programming
- Increase public awareness about TB
- Encourage communities to support TB patients
- Improve coordination among agencies working in TB
- Advocate for policy changes
- Encourage allocation of resources to TB control
- Provide lessons learned for both in-country and international programs

Source: Adapted from Adamchak S et al. *A guide to monitoring and evaluating adolescent reproductive health programs*. Washington, DC, FOCUS on Young Adults, 2000 (Tool Series 5).

The indicators can be used to assess the priorities of the implementation of the DOTS strategy and also to assess the effectiveness of overall DOTS strategy. If one component of the DOTS strategy is performing poorly in comparison with other components, then it may be desirable to allocate more resources (both human and financial) and thereby revise the relative priorities of different components in an effort to improve implementation.

The indicators can also be used by both national and international agencies to compare TB control performance across different countries. A comparison of input and process indicators would assist in identifying relative strengths and weaknesses in institutional capacity to implement DOTS, and output and outcome indicators help to show the relative progress in achieving DOTS targets. Cross-national comparisons can also assist national policy-makers in learning about innovative approaches that may be applicable in their own countries.

Finally, the indicators can be used in negotiations on TB policy among various interested parties within a country and also in policy discussions with external donors and international agencies concerning health sector reform. The indicators can provide data to enable health policy-makers to argue more persuasively and coherently, helping, for instance, to ensure that the health sector and the health status of vulnerable groups are not forgotten during times of economic reform.

To help ensure that M&E results will be used by decision-makers, program planners, and other users, a program can take a number of steps to greatly increase its capacity

for using data to identify problems and propose solutions. Some of these include the following:[17,18]

- Develop a plan for involving the potential users of the M&E results in all aspects of process. The more actively involved the users (decision-makers or health care staff) are in the planning, implementation, and analysis, the more likely they will develop a commitment to using the M&E results.

- In M&E reports, indicate clearly and succinctly major action implications arising from the M&E results.

- During supervisory visits or other appropriate venues, provide sufficient time to discuss M&E results and to develop an action plan for using the results.

### Data Dissemination

Disseminating M&E results is complex because different audiences will have different information needs. Dissemination of results will be more effective if a strategy is developed in advance. A dissemination strategy should answer the three critical questions mentioned above.[19]

Audiences can include community organizations, health providers, government officials, and social service agencies. At the regional or national level, professional colleagues, TB advocacy groups, other Ministries, policy-makers, and funding agencies may require results. Internationally, TB advocates and funding agencies will benefit from the results.

Many possible channels exist for disseminating M&E results. For some audiences, one approach may be sufficient (e.g., an all-day retreat with program staff). In other cases, multiple channels may be necessary, such as the newspaper, radio, or television, particularly for larger mass audiences. Dissemination may be carried out by staff members or may be done in collaboration with outside experts.

The most common dissemination formats are written reports, oral presentations, press releases, fact sheets, and slide or computer presentations. Visual aids such as maps, tables, charts, graphs, and photographs can be used effectively to summarize information and add a visual aspect to a written report or oral presentation.

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[17] Fisher A et al. *Handbook for family planning operations research design*. New York, The Population Council, 1991.

[18] See note 8 above.

[19] See note 17 above.

A successful dissemination strategy will identify the most effective media channel(s) to reach different audiences or users with results most relevant to their needs. Typically, a good strategy will involve multiple media channels used repeatedly over a period of time to reach the largest audience possible.

# III. MONITORING AND EVALUATION INDICATORS OF NATIONAL TUBERCULOSIS CONTROL PROGRAMS

One of the principal objectives of the compendium is to emphasize the importance of choosing standard indicators and measuring them repeatedly over time. The indicators suggested in this compendium are based on a review of country and program experiences in M&E. The strengths and weaknesses of existing measures have been identified, and new indicators have been introduced where they were considered necessary. Protocols for the measurement of all indicators are provided, and most have been field-tested.

## How to Use the Indicators

This compendium offers a wide selection of indicators. Indicators contained here can be used as they are; every effort has been made during their development to ensure that they are relevant to most situations and countries and that they provide a comprehensive view of an NTP.

Programs are not limited to the indicators listed here nor should programs attempt to use all of the indicators outlined in this compendium. Rather, it provides a menu of indicators to be used selectively as part of the M&E of NTPs, regional programs, or projects. The choice of appropriate indicators will vary according to the goals and objectives of the TB program; the costs and feasibility associated with data collection; and the usefulness of the indicators for creating and supporting TB policies, improving program implementation, and reporting on program results.

This section of the compendium is organized into 10 sections:

1. Indicators for global reporting
2. Indicators for program outcomes
3. Political commitment
4. Diagnosis and laboratories
5. Case management and treatment
6. Drug management
7. Recording and reporting
8. Supervision
9. Human resources development
10. Health systems.

The first two sections focus on the most common and well-established indicators that are globally and routinely monitored. The remaining eight sections are organized according to the major DOTS program intervention areas.

Each section includes an introduction to the topic and a set of relevant indicators. The introduction provides an overview of the importance of M&E of that particular element of the DOTS strategy, identifies key indicators, describes measurement challenges, and lists resources that may be useful for further reading on the topic.

A description of each indicator is given to provide fundamental information that will help the reader to select, calculate, collect, and interpret the indicator. Each indicator is described with a brief statement that includes the following:

- *Definition:* What is the content of the indicator and the exact calculation (i.e., numerator and denominator, if applicable)?
- *What it measures:* What will this indicator measure? Why is this indicator important? How can the results be interpreted?
- *How to measure it:* What is the method of data collection? How should this indicator be calculated?
- *Data sources:* What are the main sources of data collection?
- *Frequency & function:* How often should the data be collected? At what level should the data be collected (e.g., district)? What is the function of the indicator (e.g., routine monitoring, evaluation)?
- *Strengths & limitations:* What are the main strengths and/or limitations of the indicator?

Table 3 provides a summary of all indicators described in this section, including their calculation, data source, level of measurement (e.g., national, regional, district, facility, community), frequency (e.g., quarterly, annually, 2 to 5 years), and function (e.g., whether the indicator is used for routine reporting, process evaluation/monitoring, program review/impact evaluation, or special survey). Appendix C also provides a summary list of indicators by these functions to facilitate the selection of indicators and planning of data collection, analysis, and use. Appendix D presents a list of key indicators that make up a minimum set of indicators for assessing the performance of an NTP.

## Table 3. Summary Table of Indicators

**Compendium of Indicators for Monitoring and Evaluation of Tuberculosis Control Programs**

| Indicator | Calculation | Data Source | Level | Frequency | Function* |
|---|---|---|---|---|---|
| **1. Indicators for global reporting** | | | | | |
| 1.1 TB case detection rate† | 1) *Numerator:* Number of new TB cases detected<br>*Denominator:* Estimated number of new TB cases countrywide<br>2) *Numerator:* Number of new smear-positive TB cases detected<br>*Denominator:* Estimated number of new smear-positive TB cases countrywide<br>3) *Numerator:* Number of new smear-positive TB cases detected under DOTS<br>*Denominator:* Estimated number of new smear-positive TB cases countrywide | Quarterly reports on TB case registration, TB register, WHO estimates of incidence for each country | National | Annually | 1, 2, 3, 4 |
| 1.2 Treatment success rate‡ | *Numerator:* Number of new smear-positive pulmonary TB cases registered in a specified period that were cured plus the number that completed treatment<br>*Denominator:* Total number of new smear-positive pulmonary TB cases registered in the same period | Quarterly reports on treatment outcomes, TB register, TB treatment card | National, regional, district, facility | Quarterly, annually | 1, 2, 3, 4 |
| 1.3 DOTS coverage | *Numerator:* Population living in the area of basic management units implementing the DOTS strategy<br>*Denominator:* Total population | NTP reports, census statistics | National | Annually | 1, 2, 3 |
| 1.4 Surveillance of multidrug-resistant TB | Yes/no | NTP data and reports | National | If no, annually; if yes, every 2 to 5 years | 3, 4 |

*** Functions:** 1 = Routine Reporting, 2 = Process Evaluation/Monitoring, 3 = Program Review/Impact Evaluation, 4 = Special Survey

| Indicator | Calculation | Data Source | Level | Frequency | Function* |
|---|---|---|---|---|---|
| 1.5 HIV seroprevalence among TB patients | 1) *Numerator:* Total number of newly registered TB patients (registered over a given period of time) who are HIV positive<br>*Denominator:* Total number of newly registered TB patients (registered over the same given time period) who were tested for HIV and included in the surveillance system<br>2) *Numerator:* Total number of newly registered smear-positive TB patients (registered over a given period of time) who are HIV positive<br>*Denominator:* Total number of newly registered smear-positive TB patients (registered over the same given time period) who were tested for HIV and included in the surveillance system | Modified TB register or separate TB/HIV register, sentinel surveillance, special surveys | National, regional, district | Quarterly, annually if routinely collected otherwise 2 to 3 years | 1, 2, 3 |
| † All of the indicators commonly known as "rates" in this compendium are, technically, percentages.<br>‡ This same definition is used to calculate outcome among other cohorts (or case types), e.g., new smear-negative cases, relapse cases, treatment-after-failure cases, and treatment-after-default cases. | | | | | |
| **2. Indicators for program outcomes** | | | | | |
| 2.1 Case notification rate | 1) *Numerator:* Number of new TB cases reported in the past year (× 100,000)<br>*Denominator:* Total population in the specified area<br>2) *Numerator:* Number of new and relapse TB cases reported in the past year (× 100,000)<br>*Denominator:* Total population in the specified area<br>3) *Numerator:* Number of all TB cases reported in the past year (× 100,000)<br>*Denominator:* Total population in the specified areas | Quarterly reports on TB case registration, census statistics | National, regional, district | Annually | 1, 2, 3 |
| 2.2 Case notification rate—new smear-positive pulmonary TB cases | *Numerator:* Number of new smear-positive pulmonary TB cases reported (× 100,000)<br>*Denominator:* Total population in the specified area | Quarterly reports on TB case registration, census statistics | National, regional, district | Annually | 1, 2, 3 |

*** Functions:** 1 = Routine Reporting, 2 = Process Evaluation/Monitoring, 3 = Program Review/Impact Evaluation, 4 = Special Survey

| Indicator | Calculation | Data Source | Level | Frequency | Function* |
|---|---|---|---|---|---|
| 2.3 New pulmonary TB cases with no smear result | *Numerator:* Number of new pulmonary TB cases registered during a specified time period that do not have results of sputum smear examinations on diagnosis<br>*Denominator:* Total number of new pulmonary TB cases registered during the same period | Quarterly reports on TB case registration, TB register, TB laboratory register | National, regional, district | Quarterly, annually | 1, 2, 3 |
| 2.4 New adult smear-positive cases | *Numerator:* Number of new smear-positive adult (age 15 and older) TB cases registered during a specified time period<br>*Denominator:* Total number of new adult pulmonary TB cases registered during the same period | Quarterly reports on TB case registration, TB register | National, regional, district | Annually | 1, 2, 3 |
| 2.5 Retreatment TB cases | *Numerator:* Number of retreatment TB cases registered during a specified time period<br>*Denominator:* Total number of TB cases registered in the same period | Quarterly reports on TB case registration, TB register | National, regional, district | Quarterly, annually | 1, 2, 3 |
| 2.6 New extrapulmonary TB cases | *Numerator:* Number of new extrapulmonary TB cases registered during a specified time period<br>*Denominator:* Total number of new TB cases registered in the same period | Quarterly reports on new cases and relapses of tuberculosis, TB register | National, regional, district | Quarterly, annually | 1, 2, 3 |
| 2.7 New TB cases with no smear conversion result | *Numerator:* Number of new smear-positive pulmonary TB cases registered in a specific period that were not examined at the end of the initial phase of treatment<br>*Denominator:* Total number of new smear-positive pulmonary TB cases registered during the same period | Quarterly reports on smear conversion or program management, TB register | National, regional, district | Quarterly, annually | 1, 2, 3 |
| 2.8 Sputum conversion rate at the end of the initial phase of treatment | *Numerator:* Number of new smear-positive pulmonary TB cases registered in a specified period that were smear negative at the end of the initial phase of treatment<br>*Denominator:* Total number of new smear-positive pulmonary TB cases registered for treatment in the same period | Quarterly reports on smear conversion, TB register | National, regional, district | Quarterly, annually | 1, 2, 3 |

*** Functions:** 1 = Routine Reporting, 2 = Process Evaluation/Monitoring, 3 = Program Review/Impact Evaluation, 4 = Special Survey

| Indicator | Calculation | Data Source | Level | Frequency | Function* |
|---|---|---|---|---|---|
| 2.9 Cure rate‡ | *Numerator:* Number of new smear-positive pulmonary TB cases registered in a specified period that were cured<br>*Denominator:* Total number of new smear-positive pulmonary TB cases registered in the same period | Quarterly reports on treatment outcomes, TB register | National, regional, district | Quarterly, annually | 1, 2, 3 |
| 2.10 Treatment completion rate‡ | *Numerator:* Number of new smear-positive pulmonary TB cases registered in a specified period that completed treatment and did not meet the criteria for cure or failure<br>*Denominator:* Total number of new smear-positive pulmonary TB cases registered in the same period | Quarterly reports on treatment outcomes, TB register | National, regional, district | Quarterly, annually | 1, 2, 3 |
| 2.11 Death rate‡ | *Numerator:* Number of new smear-positive pulmonary TB cases registered in a specified period that died during treatment, irrespective of cause<br>*Denominator:* Total number of new smear-positive pulmonary TB cases registered in the same period | Quarterly reports of treatment outcomes, TB register | National, regional, district | Quarterly, annually | 1, 2, 3 |
| 2.12 Treatment failure rate‡ | *Numerator:* Number of new smear-positive pulmonary TB cases registered in a specified period that are smear positive 5 months or later after initiating treatment<br>*Denominator:* Total number of new smear-positive pulmonary TB cases registered in the same period | Quarterly reports of treatment outcomes, TB register | National, regional, district | Quarterly, annually | 1, 2, 3 |
| 2.13 Default rate‡ | *Numerator:* Number of new smear-positive pulmonary TB cases registered in a specified period that interrupted treatment for more than 2 consecutive months<br>*Denominator:* Total number of new smear-positive pulmonary TB cases registered in the same period | Quarterly reports of treatment outcomes, TB register | National, regional, district | Quarterly, annually | 1, 2, 3 |
| 2.14 Transfer-out rate‡ | *Numerator:* Number of new smear-positive pulmonary TB cases registered in a specified period that were transferred to another basic management unit and for which there is no treatment outcome information<br>*Denominator:* Total number of new smear-positive pulmonary TB cases registered during the same period | Quarterly reports of treatment outcomes, TB register | National, regional, district | Quarterly, annually | 1, 2, 3 |

*** Functions:** 1 = Routine Reporting, 2 = Process Evaluation/Monitoring, 3 = Program Review/Impact Evaluation, 4 = Special Survey

| Indicator | Calculation | Data Source | Level | Frequency | Function* |
|---|---|---|---|---|---|
| 2.15 Retreatment failure rate (chronic TB rate) | Numerator: *Number of retreatment smear-positive pulmonary TB cases registered in a specified period that are smear positive at the end of the retreatment regimen*<br>*Denominator:* Total number of retreatment smear-positive pulmonary TB cases registered in the same period | TB register | National, regional, district | Quarterly, annually | 1, 2, 3 |
| ‡ This same definition is used to calculate outcome among other cohorts (or case types), e.g., new smear-negative cases, relapse cases, treatment-after-failure cases, and treatment-after-default cases. | | | | | |
| **3. Political commitment** | | | | | |
| 3.1 TB control is among stated priorities | Yes/no | Government planning and strategy documents | National | Annually | If no = 2<br>If yes = 3 |
| 3.2 National TB policy | Yes/no | Ministry of Health (MOH) policies and/or directives regarding TB control at the national level, checklist of key policy components | National | Annually | If no = 2<br>If yes = 3 |
| 3.3 National TB program manual | Yes/no | Manual of norms and procedures for NTPs, checklist of key manual components | National | Annually | If no = 2<br>If yes = 3 |
| 3.4 NTP medium-term development plan and budget | Yes/no | NTP MDP and budget | National | Annually | If no = 2<br>If yes = 3 |
| 3.5 NTP annual work plan and budget | Yes/no | NTP annual plan and budget, MDP | National | Annually | 2, 3 |
| 3.6 Peripheral units with work plan and budget | *Numerator:* Number of peripheral management units for which a work plan and budget are available<br>*Denominator:* Total number of peripheral management units with budget and planning responsibility | Work plans and budgets, checklist of key components for annual work plans | Regional, district | Annually | 2, 3 |

*** Functions:** 1 = Routine Reporting, 2 = Process Evaluation/Monitoring, 3 = Program Review/Impact Evaluation, 4 = Special Survey

| Indicator | Calculation | Data Source | Level | Frequency | Function* |
|---|---|---|---|---|---|
| 3.7 Financial resources committed to NTP from the government | *Numerator:* Total funding from the national government for the annual plan of activities<br>*Denominator:* Total budget required for full implementation of the annual plan of activities (consistent with MDP) | Annual TB work plan and budget, MDP budget | National | Annually | 2 |
| 3.8 Annual NTP budget allocated to implement DOTS as required by medium-term development plan | *Numerator:* Total amount of funds allocated for DOTS-based TB control in the previous year's NTP budget<br>*Denominator:* Total amount of funds budgeted for DOTS-based TB control in the previous year's NTP budget as described in the annual plan | Annual NTP work plan and budget, MDP budget | National, regional | Annually | 2, 3 |
| 3.9 Key NTP staff positions filled | *Numerator:* Number of key NTP positions filled by local staff<br>*Denominator:* Total number of key NTP positions, as described in the NTP human resources development plan | NTP organizational diagram, human resource development plan | National | Annually | 2, 3 |
| 3.10 Interinstitutional coordination of TB control | Yes/no | Reports from coordination meetings, joint planning documents, recording and reporting forms | National | Annually | 2, 3 |
| 3.11 Existence and dissemination of NTP annual report | Yes/no | NTP annual reports, dissemination records | National | Annually | 2, 3 |
| 3.12 National TB control policy addresses links between TB and HIV | Yes/no | Policy audit of MOH and NTP records and policies, checklist of key components for policy | National | Annually | 2 |

*** Functions:** 1 = Routine Reporting, 2 = Process Evaluation/Monitoring, 3 = Program Review/Impact Evaluation, 4 = Special Survey

| Indicator | Calculation | Data Source | Level | Frequency | Function* |
|---|---|---|---|---|---|
| **4. Diagnosis and laboratories** | | | | | |
| 4.1 Existence of comprehensive laboratory network | Yes/no | TB laboratory register and forms | National | If no, measure annually; if yes, measure every 5 years | If no = 2<br>If yes = 3 |
| 4.2 TB microscopy coverage | 1) *Numerator:* Number of TB microscopy units that cover a population of a size within a recommended range<br>*Denominator:* Total number of TB microscopy units<br>2) *Numerator:* Total population<br>*Denominator:* Total number of TB microscopy units | Census statistics, NTP records, MOH records | National, regional, district | Annually | 3, 4 |
| 4.3 TB microscopy units with adequate workloads | *Numerator:* Number of TMUs with an average daily staff workload within a recommended range<br>*Denominator:* Total number of TMUs for which data are available | TB laboratory register | National, regional, district, facility | Annually | 1, 2, 3 |
| 4.4 TB microscopy units submitting slides for rechecking | *Numerator:* Number of TB microscopy units for which slide rechecking results are available during a specified period<br>*Denominator:* Total number of units performing TB smear microscopy during the same period | Laboratory records containing quality assurance results | National | Quarterly, annually | 2, 3 |
| 4.5 TB suspects who are smear positive | *Numerator:* Number of TB suspects found to be smear positive during a specified period<br>*Denominator:* Number of TB suspects identified clinically during the same period | TB laboratory register or cough register | National, regional, district | Quarterly, annually | 1, 2, 3 |
| 4.6 Smear-negative cases properly diagnosed | *Numerator:* Number of adult smear-negative pulmonary TB cases diagnosed with at least three negative smears and chest radiograph according to NTP-recommended algorithm during a specified time period<br>*Denominator:* Total number of adult smear-negative cases diagnosed during the same period | NTP diagnostic algorithm for smear-negative TB, TB laboratory register, TB treatment cards | District, facility | Annually | 1, 2, 3 |

*** Functions:** 1 = Routine Reporting, 2 = Process Evaluation/Monitoring, 3 = Program Review/Impact Evaluation, 4 = Special Survey

| Indicator | Calculation | Data Source | Level | Frequency | Function* |
|---|---|---|---|---|---|
| 4.7 Detected smear-positive cases registered for treatment (inverse of primary default rate) | *Numerator:* Number of new smear-positive pulmonary TB cases that have initiated treatment during a specified time period<br>*Denominator:* Total number of new smear-positive cases detected during the same period | TB laboratory register, TB register | National, regional, district, facility | Quarterly, annually | 2, 3 |
| **5. Case management and treatment** | | | | | |
| 5.1 Patients under direct observation of therapy | *Numerator:* Number of new smear-positive pulmonary TB patients who report observation of every dose of medication per NTP guidelines<br>*Denominator:* Total number of new smear-positive pulmonary TB patients interviewed regarding direct observation of therapy | Survey of TB patients and staff | National, regional, district | Annually | 2, 3, 4 |
| 5.2 New TB patients who were prescribed the correct regimen | *Numerator:* Number of new TB patients who were prescribed the correct regimen of medications during a specified period<br>*Denominator:* Total number of new TB patients who completed treatment during the same period | NTP treatment guidelines, TB register, individual medical records, facility survey | District, facility | 2 to 3 years | 2, 3, 4 |
| **6. Drug management** | | | | | |
| 6.1 Existence of a quality assurance system for drug management | Yes/no | MOH documents, National Pharmaceutical Committee documents | National | Annually | If no = 2<br>If yes = 3 |
| 6.2 Anti-TB drugs meeting international minimum quality standards | *Numerator:* Number of batches of anti-TB drugs procured locally and internationally where a batch certificate was received and showed acceptable results during a specified time period<br>*Denominator:* Total number of batches of anti-TB drugs procured during the same time period | Procurement agency records, drug registration authority records | National | Annually | 2, 3 |
| 6.3 Existence of buffer stock at central, regional, or district-level facility | Yes/no | TB drug quantification records, procurement records | National, regional, district | Annually, biannually | 2, 3 |

*** Functions:** 1 = Routine Reporting, 2 = Process Evaluation/Monitoring, 3 = Program Review/Impact Evaluation, 4 = Special Survey

| Indicator | Calculation | Data Source | Level | Frequency | Function* |
|---|---|---|---|---|---|
| 6.4 Accuracy of stock records for anti-TB drugs | *Numerator:* Number of stock records that correspond with physical counts × 100<br>*Denominator:* Total number of stock records examined | Storage facility stock cards for individual drugs, physical observations at the facility | National, regional, facility | Biannually | 2, 3 |
| 6.5 Time anti-TB drugs are out of stock—storage facilities | *Numerator:* Total number of stockout days for all first-line drugs stocked × 100<br>*Denominator:* 365 × number of anti-TB drugs | Storage facility stock cards of individual drugs | National, regional, district | Quarterly | 2, 3 |
| 6.6 Time anti-TB drugs are out of stock—treatment facilities | *Numerator:* Total number of stockout days for all first-line drugs stocked × 100<br>*Denominator:* 365 × number of anti-TB drugs in treatment facilities | Facility stock cards of individual drugs | National, regional, district | Quarterly | 2, 3 |
| 6.7 Basic management units where anti-TB drugs are available | *Numerator:* Number of basic management units visited where anti-TB drugs are present<br>*Denominator:* Total number of basic management units visited | Drugs stocked in TB BMUs | National, regional, district | Quarterly | 2, 3 |
| 6.8 Anti-TB drug samples that fail quality control tests | *Numerator:* Number of anti-TB drug samples that failed quality control testing × 100<br>*Denominator:* Total number of anti-TB drug samples tested in the country's quality control analysis laboratory | Quality control laboratory register, MOH reports | National | Annually | 2, 3 |
| **7. Recording and reporting** | | | | | |
| 7.1 Completeness of reporting to NTP | *Numerator:* Number of basic management units that submitted case-finding and treatment outcome reports to the NTP in the previous quarter<br>*Denominator:* Total number of basic management units required to submit case-finding and treatment outcome reports to the NTP each quarter | NTP statistics and reports | National, regional, district | Quarterly, annually | 1, 2, 3 |
| 7.2 Accuracy of reporting to NTP | *Numerator:* Number of TB case-finding and treatment outcome reports that were recorded completely and accurately<br>*Denominator:* Total number of TB case-finding and treatment outcome reports examined | NTP statistics and reports, TB register | National, regional, district | Quarterly | 2, 3 |

*** Functions:** 1 = Routine Reporting, 2 = Process Evaluation/Monitoring, 3 = Program Review/Impact Evaluation, 4 = Special Survey

| Indicator | Calculation | Data Source | Level | Frequency | Function* |
|---|---|---|---|---|---|
| **8. Supervision** | | | | | |
| 8.1 Supervision of DOTS implementation | *Numerator:* Number of supervisory visits performed during a specified time period<br>*Denominator:* Number of supervisory visits planned according to the annual work plan during the same period | Annual work plan, reports of the supervisory visits | National | Annually | 2 |
| 8.2 Existence of supervision guidelines | Yes/no | NTP supervision documents | National | Annually | If no = 2<br>If yes = 3 |
| **9. Human resources development** | | | | | |
| 9.1 TB microscopy units with at least one laboratory technician trained in AFB microscopy | *Numerator:* Number of TB microscopy units with at least one laboratory technician trained in AFB in the past 3 years<br>*Denominator:* Number of TB microscopy units | NTP training records, list of certified laboratory technicians and laboratory of employment, interviews with staff members | National, regional, district | Annually | 2, 3 |
| 9.2 Health care units with at least one health care professional trained in TB case detection and treatment | *Numerator:* Number of TB treatment facilities with at least one health care professional trained in TB case detection and treatment (within the past 3 years)<br>*Denominator:* Total number of TB treatment facilities | NTP training records, employee training certificates, facility training registers, interviews with staff members | National, regional, district | Annually | 2, 3 |
| 9.3 Adequate staffing at all levels to enable implementation of DOTS | Yes/no | Staffing documents or rosters, interviews with staff members | National, regional, district, facility | Annually | 2 |
| **10. Health systems** | | | | | |
| 10.1 Equitable distribution of DOTS | *Numerator:* Number of TB patients living in poverty notified under DOTS in specified time period<br>*Denominator:* Total number of TB patients notified under DOTS in specified time period × the percentage of the population living in poverty | Quarterly reports on TB case registration, census statistics, special surveys | National | Annually | 2, 3, 4 |

*** Functions:** 1 = Routine Reporting, 2 = Process Evaluation/Monitoring, 3 = Program Review/Impact Evaluation, 4 = Special Survey

# 1. Indicators for Global Reporting

## Introduction

The indicators described in this section are based on data reported by NTPs. Data are used to monitor progress in DOTS expansion and achievement at national and global levels of the WHO targets for TB control: treatment success of at least 85% and case detection rate of at least 70%. National data reported to WHO allow comparisons between countries, monitoring trends in TB case reporting and age/sex distribution of pulmonary smear-positive cases, and comparisons of the results of DOTS with other strategies in routine conditions. WHO requests results on these indicators as a means to encourage their adoption and use at the national level, as well as to enable global TB surveillance and intercountry comparisons. These indicators are, however, first and foremost critical to monitoring, evaluation, and problem-solving at national and local levels.

Data reported to WHO are complemented by reports of joint reviews of national TB programs, involving national and external experts, following the guidelines produced by WHO and the UNION. The information and conclusions, together with epidemiological estimates, are published annually in a WHO report on global tuberculosis control.

Indicators 1.1 to 1.3 are reported to WHO every year by national TB programs (or relevant public health authorities) and are included in the annual WHO report on global TB control. These indicators measure NTP progress towards international targets for case detection, treatment success, and DOTS coverage.

Indicators 1.4 and 1.5 provide important information on whether countries are aware of the prevalence of MDR-TB and HIV among TB cases. WHO has recently published criteria to provide guidance to NTPs on the type of collaborative activities that should be pursued with the national AIDS program, and these programs vary from country to country. However, it is important to monitor whether or not NTPs are performing surveillance to estimate the prevalence of HIV among TB cases, and vice versa, because they need these data in order to make decisions with regard to collaborative programs. Additionally, although not every country will pursue activities to address drug-resistant TB, every country should be tracking the prevalence of MDR-TB among pulmonary TB cases so that action can be taken if necessary. This has important implications for advocacy activities, planning resources, and the design and implementation of appropriate TB control activities.

## Indicators

- TB case detection rate
- Treatment success rate
- DOTS coverage
- Surveillance of multidrug-resistant TB
- HIV seroprevalence among TB patients

## Resources

*A guide to monitoring and evaluation for collaborative TB/HIV activities*. Field test version. Geneva, World Health Organization, 2004 (WHO/HTM/TB/2004.342, WHO/HIV/2004.09).

Corbett EL et al. The growing burden of tuberculosis: global trends and interactions with the HIV epidemic. *Archives of Internal Medicine*, 2003, 163:1009–1021.

Dye C et al. Global burden of tuberculosis: estimated incidence, prevalence and mortality by country. *Journal of the American Medical Association*, 1999, 282:677–686.

Enarson D et al. *Management of tuberculosis: a guide for low income countries*. Paris, International Union Against Tuberculosis and Lung Disease, 2000.

*Global tuberculosis control: surveillance, planning, financing. WHO report 2003*. Geneva, World Health Organization, 2003 (WHO/CDS/TB/2003.316).

*Global tuberculosis control: surveillance, planning, financing. WHO report 2004*. Geneva, World Health Organization, 2004 (WHO/HTM/TB/2004.331).

*Treatment of tuberculosis: guidelines for national programs*. Geneva, World Health Organization, 2003 (WHO/CDS/TB/2003.313).

**Indicator 1.1**

# TB CASE DETECTION RATE

## Definition

The percentage of TB cases detected (diagnosed and reported to the national health authority) among the total number of TB cases estimated to occur countrywide each year. This indicator can be analyzed in three ways: in terms of all forms of TB (i.e., pulmonary and extrapulmonary), in terms of smear-positive TB cases only, and in terms of smear-positive TB cases detected under DOTS. The corresponding definitions follow:

1. Case detection rate: all forms

$$\frac{\text{Number of new TB cases detected}}{\text{Estimated number of new TB cases countrywide}} \times 100$$

2. Case detection rate: new smear-positive cases

$$\frac{\text{Number of new smear-positive TB cases detected}}{\text{Estimated number of new smear-positive TB cases countrywide}} \times 100$$

3. Case detection rate: new smear-positive cases reported under DOTS

$$\frac{\text{Number of new smear-positive TB cases detected under DOTS}}{\text{Estimated number of new smear-positive TB cases countrywide}} \times 100$$

## What It Measures

This indicator measures an NTP's ability to diag100nose and collect data on TB cases. A high case detection rate will mean that transmission by undiagnosed infectious TB patients is curtailed, leading to the impact of less TB disease and less TB mortality in the population. A high case detection outcome relies, in turn, on a number of processes, for example, identification of TB suspects by clinicians, laboratory services that are adequate (in terms of equipment, staffing, geographical distribution, and quality control), and completeness of reporting.

There is an emphasis on smear-positive cases (definitions 2 and 3 above) because these are the "bacteriologically confirmed" cases that even the most basic TB control programs should be able to identify and because they represent infectious cases of TB that are of the highest priority in terms of TB control. There is an emphasis on detection

under DOTS (definition 3) because detection in the context of an internationally recommended TB control strategy is important. Where DOTS is implemented widely, detection under DOTS will approach detection countrywide. Reasons for low TB case detection countrywide include limited access or utilization of health facilities, insufficient clinical suspicion and referral of TB suspects for diagnosis, incomplete disease reporting within a given information system, and lack of coordination among parallel disease reporting systems (e.g., dispensary system versus that of hospitals or private practitioners, or prisons or other institutions). Incomplete and/or uncoordinated reporting often accounts for a large gap in detection.

Reasons for low TB case detection under DOTS specifically include all of the above plus incomplete implementation of DOTS. In some situations where all of the above issues have been addressed, at least in the public sector, low case detection may prompt supplemental case-finding activities, for example, bringing private and nongovernmental organization (NGO) providers into the DOTS program.

Reasons for low smear-positive TB case detection may include all of the above, plus inadequate use or functioning of smear microscopy services. For example, a sufficient number of sputum samples may not be obtained, a smear examination may not be requested on sputum samples submitted for culture, laboratories may not be equipped with all reagents to perform the smear, or laboratory staff may not be sufficiently trained to identify a positive smear.

On the other hand, the smear-positive case detection rate may be high if reporting requirements stipulate that only pulmonary cases need to be reported or if reporting forms sent to the national level do not distinguish new smear-positive cases from other cases (neither of these scenarios is advised). The smear-positive case detection rate may be high if there is some secondary motive or "gain" involved (e.g., bounties paid to clinicians for smear-positive cases only, or free treatment allocated to smear-positive cases only). Smear-positive case detection may also be high if laboratory staff are not adequately trained in the staining and reading of slides.

The TB case detection rate (whether all forms or smear-positive cases) may exceed 100% during the first few years of rapid DOTS implementation/expansion because of diagnoses among a backlog of prevalent new cases (never diagnosed previously) and perhaps also a backlog of "relapse" cases (previous episode of TB presumably cured but suboptimally treated outside the DOTS program). In a more "steady-state" scenario, the TB case detection rate may exceed 100% because of overdiagnosis of TB (a large proportion of extrapulmonary cases is sometimes a clue in this regard). It is also possible for the TB case detection to exceed 100% if TB incidence has been

underestimated by WHO. (Dye and others provide an explanation of how WHO estimates are made.[1])

## How to Measure It

The numerator is available from the TB register or quarterly case detection reports. "All forms" refers to all sites—pulmonary and extrapulmonary. By convention, the numerator includes relapses as well as new cases, on the grounds that "relapse" cases may represent exogenous reinfections and can therefore be counted as new "events" in surveillance (erring on the side of inclusiveness). In contrast to new and relapse cases, the various other cases registered (all being "retreatment" case types) do not represent new disease episodes or events; they represent ongoing events that—in theory—were already "reported" in the surveillance system as new cases.

The numerator for detection under DOTS depends on whether a basic management unit is implementing the DOTS strategy. Cases are attributed to DOTS if they are reported from a BMU implementing DOTS. A BMU is a unit where a TB register is kept and where quarterly reports are made. It is internationally recommended to have one BMU per 50,000 to 150,000 people, up to 300,000 for large cities. Implementation of DOTS means that all components of the internationally recommended approach to TB control are in place:

- Political commitment
- Uninterrupted drug supply
- Use of smear microscopy in diagnosing TB cases
- Standardized short-course treatment regimens
- Direct observation of treatment
- Monitoring of treatment outcomes for 100% of patients with TB.

The NTP should have a record of the year and quarter when each BMU officially began implementation of the DOTS strategy, as per national guidelines. It should also have available (from the appropriate Ministry) the populations living in these BMUs.

The denominator is a WHO estimation of new cases—pulmonary and extrapulmonary—based on a mathematical model that takes into account all available data, including case notifications, an estimate of the completeness of notifications, the trend in notifications, TB mortality in the population, studies on TB disease prevalence and risk of infection, HIV prevalence, duration of TB illness, likelihood of receiving TB treatment in different sectors, and case fatality given different treatment scenarios. In

[1] Dye C et al. Global burden of tuberculosis: estimated incidence, prevalence and mortality by country. *Journal of the American Medical Association*, 1999, 282:677–686.

essence, the starting point for the model depends on the information available for any given country, and the remaining elements in the model are either imputed from regional averages or generated as outputs of the model. These estimations are reported every year by WHO in the annual report on global TB control.

### Data Sources

- Quarterly reports on TB case registration
- TB register
- WHO estimates of incidence for each country

### Frequency & Function

This indicator should be calculated annually. Seasonal fluctuations in TB incidence and care-seeking behavior may affect the numerator if it is based on a period of data collection that is less than 12 months. This indicator should be calculated at the national level only because the WHO estimated incidence for each country applies only to the country as a whole.

### Strengths & Limitations

As noted above, the case detection numerator may be affected by a number of factors; these are potential problems that are "indicated" by the analysis, rather than limitations of the indicator itself (e.g., underreporting of cases to the NTP). Limitations of the indicator are that it can only be used at the national level and that it can only be used on an "annualized" basis. In addition, there are certain limitations inherent in the calculation of DOTS coverage and in WHO's estimate of incidence.

The limitation of use only at the national level (countrywide analysis) is related to the accuracy and appropriateness of the denominator, WHO's estimated incidence for the country as a whole. There may be real differences in TB epidemiology in urban/rural areas and/or at subnational levels, which mean that the national estimate should not be used at subnational levels. In essence, the subnational unit calculating detection rate on the basis of the national estimate may be simply dividing a real number (registered cases) by a meaningless constant. Inasmuch as the meaningless constant is stable, following the trend of this quotient is not harmful (although it would be preferable to divide by the population instead). The real danger is that these subnational units might be congratulated for having met the target (or, worse, admonished for not having met the target), leading to laxity or despondency (respectively), when in fact the truth is simply not known. In short, subnational units are obliged to focus not on absolute levels but rather on trends—of whatever they choose to monitor (absolute number of cases, cases divided by the population, or cases divided by a potentially meaningless constant).

**Indicator 1.2**

# TREATMENT SUCCESS RATE

## Definition

The percentage of a cohort of TB cases registered in a specified period that successfully completed treatment, whether with bacteriologic evidence of success ("cured") or without ("treatment completed"). The cohort of new smear-positive cases successfully treated is calculated using the following numerator and denominator:

$$\frac{\text{Number of new smear-positive pulmonary TB cases registered in a specified period that were cured plus the number that completed treatment}}{\text{Total number of new smear-positive pulmonary TB cases registered in the same period}} \times 100$$

The same definition is used to calculate success among other cohorts (or case types) (e.g., new smear-negative cases, relapse cases, treatment-after-failure cases, treatment-after-default cases).

## What It Measures

This indicator measures a program's capacity to retain patients through a complete course of chemotherapy with a favorable clinical result. It is an outcome indicator (in the logical framework sense), and it is noteworthy because it is the only outcome indicator that can (and should) be used at all levels (e.g., from operational level to international level). There is a direct and immediate link between this outcome of treatment success and the impact of reduced TB mortality. This outcome is, in turn, influenced by a variety of factors (e.g., uninterrupted drug supply, supportive environment for the patient), which are assessed via certain process indicators described in this compendium.

For new smear-positive cases, there is a target of 85% treatment success, based on the assumption of what can be reasonably achieved assuming the baseline proportion of unfavorable outcomes (death and failure and default) to be about 15%. The 85% level formally became a global target via the World Health Assembly resolution of 1991 (originally 85% cure, later 85% success). It is arguable that populations with high HIV prevalence or with a preponderance of older adults may have difficulty reaching the 85% target because of higher percentages of death outcomes.

For pulmonary smear-positive cases, the cure rate is more trustworthy—or more valuable—than the success rate because patients who completed treatment but who do not have bacteriological confirmation of cure could conceivably still have smear-positive TB disease. The large majority of successfully treated cases should have bacteriological confirmation of cure.

Success among retreatment case types is normally lower than that for new patients—more so for treatment-after-failure (because previous failure may have been due to drug resistance) and treatment-after-default cases (because cases that defaulted previously are likely to have poor compliance and/or drug resistance) than for relapse cases. There is no international target for success in retreatment cohorts, but it is recommended that success be monitored in each of these cohorts.

This indicator relies on accuracy and effort in the determination of treatment outcomes at the facility level. In a program where there is no mechanism for treatment facilities to communicate with each other, for instance, the success rate may be low because of a preponderance of unknown outcomes related to transferring patients.

### How to Measure It

At the end of the treatment course, one of six treatment outcomes is recorded for each sputum smear-positive TB case: cured, treatment completed, died, failed, defaulted, or transferred out, which is recorded in the TB register. The numerator for this indicator is treatment success, which is the sum of cases registered in a specified period (e.g., quarter or year) and recorded with the treatment outcome, either "cure" or "treatment completed." The denominator is the number of cases. Because of the applicability of this indicator to the lowest level, measurement has always been based on 100% of TB cases.

### Data Sources

- Quarterly reports on treatment outcomes
- TB register
- TB treatment card

### Frequency & Function

This indicator should be calculated on a quarterly and annual basis.

### Strengths & Limitations

As noted, the strength of this indicator is the fact that it can be used at all levels. All information needed to calculate the indicator is available at the local level; there is no need to refer to an estimate. At higher levels, this indicator is affected by completeness of reporting; that is, if reporting on cases registered is more complete than reporting (1

year later) on treatment outcomes, then the outcomes of some cases in the denominator will be unaccounted for.

Another important limitation is that success (and other treatment outcomes monitored routinely in TB programs) is an outcome of treatment regimens, not patient results. Although it might be useful to analyze a cohort of TB patients in terms of survival or TB-free status at a given point in time (e.g., 12 months, 24 months), the routine TB monitoring system was not designed to facilitate such an analysis. In the routine TB monitoring system, an outcome is an irrevocable event (or status assignment) that signals an end of the current treatment regimen. An end is declared because the regimen was completed (cured, completed), because the regimen is no longer applicable (failure, default), or because no information could be obtained (death, transfer out, and not evaluated). Obviously, some cases with recorded outcomes of failure or default may go on to be cured (after reregistration for retreatment regimens), and some cured cases may go on to relapse. Some default cases are never seen again and may therefore have died or spontaneously healed or found treatment elsewhere. The only status assignment serving both types of analysis (routine monitoring versus survival analysis) is death. Where there is interest in monitoring outcomes of patients (as distinct from outcomes of regimens), more sophisticated relational linkages must be introduced into the record-keeping system.

**Indicator 1.3**

# DOTS COVERAGE

## Definition

Percentage of the population living in the area of basic management units implementing the DOTS strategy

$$\frac{\text{Population living in the area of basic management units implementing the DOTS strategy}}{\text{Total population}} \times 100$$

## What It Measures

This indicator measures the extent of a country's population "covered" by DOTS. The goal is to cover 100% of the population.

## How to Measure It

A basic management unit is a unit where a TB register is kept and where quarterly reports are made. It is internationally recommended to have one BMU per 50,000 to 150,000 people, up to 300,000 for large cities. Implementation of DOTS means that all components of the internationally recommended approach to TB control are in place:

- Political commitment
- Uninterrupted drug supply
- Use of smear microscopy in diagnosing TB cases
- Standardized short-course treatment regimens
- Direct observation of treatment
- Monitoring of treatment outcomes for 100% of patients with TB.

Obviously, the implementation of these components is a serious undertaking, involving training of staff in the use of new definitions and reporting forms and an approach to diagnosing and treating and supporting the patient. It may also involve considerable planning and collaboration of various members of the community (which, in itself, demonstrates commitment), and it may involve considerable renovation and equipping of laboratories and treatment facilities.

The NTP should have a record of the year and quarter when each BMU officially began implementation of the DOTS strategy, as per national guidelines. It should also have available (from the appropriate Ministry) the populations living in these BMUs.

## Data Sources

- NTP records
- Census statistics

## Frequency & Function

This indicator should be measured annually.

## Strengths & Limitations

It must be emphasized that DOTS population "coverage" does not measure "access" to care. DOTS coverage is a simple indicator that is particularly useful in the early stages of DOTS implementation. But it is also somewhat simplistic, as it only measures the presence or absence of DOTS services within a given administrative area; it does not provide information on geographic distance or financial or other barriers to care. Also, "DOTS" implementation in a given unit does not depend on having reached a certain level of performance; it is expected that the performance of DOTS units will improve during the early stages of being called a "DOTS" unit. Overall, it is fairly assumed that BMUs implementing DOTS have a higher level of performance and TB patients are getting a better standard of care.

All countries may not always follow the same process in designating BMUs performing DOTS. For instance, a unit that services 2 million people with only three diagnostic facilities and only one part-time coordinator/supervisor who has no travel budget clearly should not be considered to perform DOTS, no matter how much training has been done. "BMU DOTS" designation may wrongly imply that TB control in the community at large is well coordinated (e.g., between dispensaries and hospitals and specialty clinics and private practitioners).

**Indicator 1.4**

# SURVEILLANCE OF MULTIDRUG-RESISTANT TB

## Definition

The national TB control program assesses the prevalence of multidrug-resistant TB at least once within a 5-year period. This is a yes/no indicator.

## What It Measures

This indicator measures the availability of information on drug susceptibility in new and previously treated TB patients, mainly with regards to multidrug resistance (i.e., resistance to at least isoniazid and rifampicin), on the basis of national or subnational representative surveys. This information is useful for monitoring the quality of the program because MDR-TB prevalence rates indicate the potential effectiveness of the treatment regimens, the expected load of MDR-TB patients for program decisions on treatment implementation of chronic and MDR-TB patients, and the need of resources.

## How to Measure It

A "yes" response to this indicator should be based on the availability of data from a national or subnational representative survey following protocols and quality assurance mechanisms of the WHO/International Union Against Tuberculosis and Lung Disease Global Project on Anti-Tuberculosis Drug Resistance Surveillance.[1]

## Data Sources

- NTP data and reports

## Frequency & Function

If this indicator is "no," then this indicator should be measured every year until MDR-TB surveillance has taken place within the country. If the indicator is "yes," then this indicator should be measured every 2 to 5 years to monitor whether MDR-TB surveillance is taking place within the recommend timeframe.

## Strengths & Limitations

The information is useful for planning and monitoring. However, as many yes/no indicators, this indicator measures only whether the surveillance takes place, not the quality of the data collected or the strength of the methodology used to collect the data.

[1] WHO/IUATLD Global Project on Anti-Tuberculosis Drug Resistance Surveillance. *Anti-tuberculosis drug resistance in the world. Report 2. Prevalence and trends.* Geneva, Communicable Diseases, World Health Organization, 2000 (WHO/CDS/TB/2000.278).

A major limitation of this indicator is the narrow range within which to act on its results. The available medications that can be effectively used for standard case management at the community level are severely limited, resulting in a very limited possible policy response where significant problems with MDR-TB are detected.

**Indicator 1.5**

# HIV SEROPREVALENCE AMONG TB PATIENTS

## Definition

Number of all newly registered TB patients who are HIV positive, expressed as a percentage of all registered TB patients.

1. All cases:

$$\frac{\text{Total number of newly registered TB patients (registered over a given period of time) who are HIV positive}}{\text{Total number of newly registered TB patients (registered over the same given time period) who were tested for HIV and included in the surveillance system}} \times 100$$

2. Smear-positive cases:

$$\frac{\text{Total number of newly registered smear-positive TB patients (registered over a given period of time) who are HIV positive}}{\text{Total number of newly registered smear-positive TB patients (registered over the same given time period) who were tested for HIV and included in the surveillance system}} \times 100$$

## What It Measures

Surveillance of HIV prevalence among TB patients will give information about the epidemics of both TB and HIV. In particular, it gives an indication of the degree of overlap in the epidemics in any given setting, and when compared with the HIV prevalence in the general population, it will give an indication of the contribution that HIV is making to the TB epidemic in any given setting. Estimating the prevalence of HIV among TB patients is an important step in planning TB control activities, planning and targeting integrated TB and HIV activities, and monitoring the effectiveness of these activities over time.

## How to Measure It

Ideally, all newly registered patients with TB, in accordance with the standard international case definition, should be considered for HIV surveillance. However, it is important to focus on new smear-positive TB patients because of the specificity of the diagnosis of this group. Countries with scarce resources and where the HIV epidemic

state is either low or concentrated may also choose to only include patients between the ages of 15 and 59 years. There are three main methods for surveillance of HIV among TB patients: data from routine testing of TB patients for HIV, sentinel methods, and special surveys. Selecting the appropriate strategy for HIV surveillance among TB patients will depend on the existing surveillance system, the underlying HIV epidemic state of a country, the status of implementation of antiretroviral therapy, and the overall TB situation.

## Data Sources

- Routine data from HIV counseling and testing of TB patients collected continuously in a modified TB register or a separate TB/HIV register
- Sentinel surveillance
- Special surveys

## Frequency & Function

In the absence of a national recording and reporting system where data are continuously collected and reported quarterly, data should be collected every 2 to 3 years. In countries that have a low HIV prevalence level in TB patients (less than 5%) and that have a stable and low HIV epidemic state and TB burden in the general population, periodic surveys may be repeated at 5-year intervals. In resource-poor countries, where the HIV and TB burden in the general population may be concentrated or generalized, but where the institution of more systematic methods of surveillance is not possible, tailored periodic surveys should be undertaken at least every 3 to 5 years.

## Strengths & Limitations

Measuring HIV seroprevalence among TB patients can inform the targeting of resources and the planning of activities for people with HIV and TB and for monitoring the effectiveness of these activities over time. It can raise both political and professional awareness of HIV-related TB and the need for a collaborative approach to addressing the problem. It is also helpful to corroborate surveillance data on HIV prevalence in the general population obtained from other sources. In states with a low HIV epidemic, it will provide an early indication of changes in the HIV epidemic, alerting policy-makers of the need for joint strategies. In concentrated or generalized HIV epidemics, it will help in assessing the impact of HIV on TB and will monitor the effectiveness of joint strategies to reduce the burden of HIV and TB. The use of unlinked anonymous surveys to derive such information is increasingly criticized because of the advantages of knowing one's status and the ethics of carrying out HIV testing in patients not offered voluntary counseling and testing (VCT).

# 2. Indicators for Program Outcomes

## Introduction

The indicators in this section are routinely calculated by TB control programs at district, regional, and national levels, and they are based on data from the TB register and quarterly reports on TB case registration, smear conversion, and treatment outcomes. (Appendix B contains examples of these forms.) They are used to monitor progress towards achievement of the national targets for case detection and treatment outcomes and to monitor program quality and effectiveness.

This section includes treatment outcome indicators (Indicators 2.9 through 2.15) that are calculated with cohort analysis. A cohort analysis is a review of patient outcomes using a set cohort, that is, a cohort (or group of individuals) that started treatment during the same time period (usually during the same quarter). The outcomes of each patient in the cohort are reviewed after a sufficient amount of time for all of them to have completed therapy (allowing for interruptions and restarts). This is typically somewhere between 12 to 15 months after the last date a patient could have started therapy. Each patient should have had a treatment outcome recorded by that time in the TB register. Cohort analysis is the key management tool for evaluating the effectiveness of the TB control program. It allows the identification of problems so that the program can institute appropriate action to overcome them and improve program performance. Cohort analyses are conducted on a regular basis as part of routine reporting.

## Indicators

- Case notification rate
- Case notification rate—new smear-positive pulmonary TB cases
- New pulmonary TB cases with no smear result
- New adult smear-positive cases
- Retreatment TB cases
- New extrapulmonary TB cases
- New TB cases with no smear conversion result
- Sputum conversion rate at the end of the initial phase of treatment
- Cure rate
- Treatment completion rate
- Death rate
- Treatment failure rate
- Default rate
- Transfer-out rate
- Retreatment failure rate (chronic TB rate)

## Resources

Enarson D et al. *Management of tuberculosis: a guide for low income countries*. Paris, International Union Against Tuberculosis and Lung Disease, 2000.

*Global tuberculosis control: surveillance, planning, financing*. *WHO report 2004*. Geneva, World Health Organization, 2004 (WHO/HTM/TB/2004.331).

Pio A, Chaulet P. *Tuberculosis handbook*. Geneva, World Health Organization, 1998 (WHO/TB/98.253).

*Treatment of tuberculosis: guidelines for national programs*. Geneva, World Health Organization, 2003 (WHO/CDS/TB/2003.313).

**Indicator 2.1**

# CASE NOTIFICATION RATE

## Definition

The number of TB cases reported to the NTP per year per 100,000 population.

1. Case notification rate: new cases

$$\frac{\text{Number of new TB cases reported in the past year}}{\text{Total population in the specified area}} \times 100{,}000$$

2. Case notification rate: new and relapse cases

$$\frac{\text{Number of new and relapse TB cases reported in the past year}}{\text{Total population in the specified area}} \times 100{,}000$$

3. Case notification rate: all cases

$$\frac{\text{Number of all TB cases reported in the past year}}{\text{Total population in the specified area}} \times 100{,}000$$

## What It Measures

The indicator provides information on the burden of disease, number of cases to be treated, and resources required. Information on the true incidence or prevalence of TB disease is unlikely to be available. However, the number of cases reported can be compared with incidence estimates to detect deficiencies in case detection and registration. Trends over time in case notification usually indicate changes in program coverage and capacity to detect TB cases; at high levels of case detection, the indicator reflects changes in the prevalence of TB in the community. The case notification rate provides data for program planning and M&E purposes, and it should be used to guide these activities. For example, an upward trend in case notification rates can reflect an improvement in program performance or, in some cases, the impact of the HIV/AIDS epidemic. When possible, this indicator should also be analyzed by age and gender.

## How to Measure It

The numerator is the number of newly notified TB patients per year, which can be obtained from reports at the national level for the previous year. The denominator, the total number of population in a specific area, can be obtained from census data.

## Data Sources

- Quarterly reports on TB case registration
- Census statistics

## Frequency & Function

This indicator should be calculated on an annual basis.

## Strengths & Limitations

Case notification represents only a subset of the true number of cases arising in a country because of incomplete coverage by health services, inaccurate diagnosis, or deficient recording and reporting. Notifications reported by MOH often do not include cases managed by the private sector; this emphasizes the need to improve efforts to gather data from the private sector. Although in most countries, case notifications underrepresent the true burden of disease, they often represent the most useful data for estimating incidence. The number of total TB cases is influenced by the capacity to diagnose extrapulmonary and smear-negative pulmonary cases (availability of culture and other diagnostic methods), by clinician skill in interpreting chest X-ray abnormalities, by the capacity and criteria to diagnose TB in children, and by the coverage of reporting of TB in children.

**Indicator 2.2**

# CASE NOTIFICATION RATE—NEW SMEAR-POSITIVE PULMONARY TB CASES

## Definition

The number of new smear-positive pulmonary TB cases reported to the NTP per year per 100,000 population.

$$\frac{\text{Number of new smear-positive pulmonary TB cases reported}}{\text{Total population in the specified area}} \times 100{,}000$$

## What It Measures

The numerator provides information on the number of infectious TB cases detected. Because effective treatment of infectious TB patients reduces TB transmission, early detection is one of the main strategies of TB control, and the indicator measures the program's capacity to identify those sources. Information on true incidence or prevalence of TB disease is unlikely to be available. However, the number of cases reported can be compared with incidence estimates to detect deficiencies in case detection and registration. Trends over time in case notification usually indicate changes in program coverage and capacity to detect TB cases; at high levels of case detection, the indicator reflects changes in the prevalence of TB in the community. Additionally, it provides data for program planning and M&E purposes, and it should be used as a measure to guide these activities. For example, an upward trend in case notification rates can reflect an improvement in program performance or, in some cases, the impact of the HIV/AIDS epidemic. When possible, this indicator should also be analyzed by age and gender.

## How to Measure It

The numerator is the total number of notified smear-positive TB patients per year, which can be obtained from reports at the national level for the previous year. The denominator can be obtained from census data.

## Data Sources

- Quarterly reports on TB case registration
- Census statistics

## Frequency & Function

This indicator should be calculated on an annual basis.

## Strengths & Limitations

The indicator is a direct measure of program capacity to identify infectious cases. The number of new pulmonary smear-positive TB cases provides a better comparison and trends over time between countries and areas, as compared with the number of total cases, because it uses a single, objective method (sputum microscopy). However, case notification represents only a subset of the true number of cases arising in a country because of incomplete coverage by health services or deficient recording and reporting. Although, in most countries, case notifications underrepresent the true burden of disease, they often represent the most useful data for estimating incidence.

**Indicator 2.3**

# NEW PULMONARY TB CASES WITH NO SMEAR RESULT

## Definition

The percentage of new pulmonary cases registered that do not have results of sputum smear examinations on diagnosis.

$$\frac{\text{Number of new pulmonary cases registered during a specified time period that do not have results of sputum smear examinations on diagnosis}}{\text{Total number of new pulmonary TB cases registered during the same period}} \times 100$$

## What It Measures

This is an indicator of program quality and diagnostic procedures. It reflects medical diagnostic practices (use of radiological diagnosis without use of sputum microscopy). The ideal is to have no adult patients with pulmonary TB diagnosed without sputum smear examination, and the smear results of all patients recorded in the register. Exceptions include young children or HIV-positive patients who are generally unable to produce sputa and very ill individuals for whom sputa could not be collected on diagnosis and initiation of treatment was very urgent. A proportion of patients without smear results (particularly in adults) requires further study to determine the reason why there are no results. If this is the common medical practice, information and training of medical practitioners should be provided. If the reason is poor transfer or recording of data from the laboratory register to the TB register, staff should be retrained and monitoring should be strengthened. This indicator may be high if the program is using culture examinations.

## How to Measure It

The quarterly report on case registration provides the base data. If the result is not satisfactory (high proportion without smear results), the TB register, treatment cards, and laboratory register should be checked. If the transfer of data is correct, the medical practitioners who are not using the recommended diagnostic algorithm should be identified and retrained, or general information for practitioners can be developed and distributed.

## Data Sources

- Quarterly reports on TB case registration
- TB register
- TB laboratory register

## Frequency & Function

This indicator should be calculated on a quarterly and annual basis.

## Strengths & Limitations

The indicator is very useful for monitoring trends in areas where medical practice relies mainly on radiological examination for diagnosis of pulmonary TB. A limitation is that exceptions are acceptable (particularly in children).

**Indicator 2.4**

# NEW ADULT SMEAR-POSITIVE CASES

## Definition

The percentage of new adult smear-positive TB cases out of all adult pulmonary TB cases.

$$\frac{\text{Number of new pulmonary smear-positive adult (age 15 and older) TB cases registered during a specified time period}}{\text{Total number of new adult pulmonary TB cases registered during the same period}} \times 100$$

## What It Measures

The indicator assesses the adequacy of smear diagnosis for TB suspects, specifically the utilization of laboratory services by diagnosing clinicians for determining whether or not a TB suspect has infectious TB. It reflects the development of program screening of TB suspects with sputum smear microscopy, as well as the relative weight of medical diagnosis of pulmonary TB without microscopy examination or with negative smears. In program conditions in countries with medium or high TB burden, over two-thirds of pulmonary TB in adults should present with positive smears (the remainder being either culture-positive or culture-negative pulmonary TB). The proportion of children with smear-positive pulmonary TB is quite low. Although the diagnosis of TB can be made in smear-negative individuals (particularly in children and those who had never been treated), the absence of bacteriological examination is not an acceptable medical practice in the diagnosis of pulmonary TB in adults. Under program conditions, when microscopy laboratory services are available and diagnostic criteria are properly applied, pulmonary TB smear-positive cases represent at least 65% of the total pulmonary TB cases in adults and 50% or more of all TB cases. These proportions may be lower in populations with high HIV incidence.

## How to Measure It

The indicator is calculated on the basis of information in the TB registers at diagnostic centers visited. A standard case-finding report for the most recent quarter should be prepared to determine the number of smear-positive adult (age 15 and older) pulmonary TB cases; this is the numerator. The total number of all adult pulmonary TB cases is the denominator. The indicator can be calculated for each center individually or for all centers visited.

## Data Sources

- Quarterly reports on TB case registration
- TB register

## Frequency & Function

This indicator should be collected and reported quarterly and annually for monitoring purposes.

## Strengths & Limitations

The proportion of smear-positive cases should be interpreted in light of HIV prevalence, since in areas with a high proportion of HIV-associated TB, there will be comparatively more smear-negative cases than in areas with low prevalence. The indicator is somewhat dependent on the availability of X-ray facilities at the diagnostic centers. In locations where X-ray facilities are available, one would expect results at the lower end of the indicator range; where no X-ray facilities are available, results would typically be expected at the higher end of the range.

**Indicator 2.5**

# RETREATMENT TB CASES

## Definition

The percentage of TB cases classified as retreatment in the past year.

$$\frac{\text{Number of retreatment TB cases registered during a specified time period*}}{\text{Total number of TB cases registered in the same period}} \times 100$$

**Retreatment includes all previously treated patients (treatment-after-default, treatment-after-failure, and relapse cases) who are newly registered for treatment.*

## What It Measures

This indicator represents the percentage of TB patients who require more extensive treatment and should be suspected of having acquired drug resistance. Ineffective treatment or incorrect administration of medication may result in a large proportion of retreatment cases, which points to deficiencies in the medication used and/or nonadherence to D.O.T. on the part of patients and providers. This indicator indirectly reveals the effectiveness of the NTP, since under a well-functioning TB control program, retreatment cases should make up a smaller proportion than new cases. Additionally, relapse is more likely in patients with HIV, so the indicator should be interpreted in light of HIV prevalence. There are many reasons why retreatment is necessary, including nonadherence to D.O.T. on the part of patients and providers, low-quality anti-TB drugs, and the presence of drug-resistant TB. In newly implemented DOTS programs, a high proportion (up to one-third) of the cases can be retreatment cases due to failures in treatment quality in previous program strategies. This proportion is reduced in a few years to 10 to 20% with good program quality, particularly because of a reduction in defaulters.

## How to Measure It

The numerator is the total number of retreatment TB cases, which can be obtained from the TB register or from the quarterly report on TB registration. The denominator, the total number of TB cases registered during a specified period, can also be obtained from the TB register.

## Data Sources

- Quarterly reports on TB case registration
- TB register

## Frequency & Function

This indicator should be measured on a quarterly and annual basis.

## Strengths & Limitations

This indicator relies on the accuracy of case definition at the time of diagnosis and subsequent reporting to the NTP. This indicator is useful for following trends within a country or region and for cross-country comparisons.

**Indicator 2.6**

# NEW EXTRAPULMONARY TB CASES

## Definition

The percentage of TB cases with site of disease defined as extrapulmonary in the past year.

$$\frac{\text{Number of new extrapulmonary TB cases registered during a specified time period}}{\text{Total number of new TB cases registered in the same period}} \times 100$$

## What It Measures

Extrapulmonary TB is defined as a disease of organs other than the lungs (e.g., pleura, lymph nodes [including intrathoracic lymph nodes], abdomen, genitourinary tract, skin, joints and bones, meninges). Diagnosis should be based on one or more culture-positive specimens or on histological or strong clinical evidence consistent with active extrapulmonary disease accompanied by a clinician's decision to treat with a full course of anti-TB medications. When both pulmonary and extrapulmonary disease are present, the TB case should be classified as pulmonary. Cases of miliary TB should be classified as pulmonary because of the involvement of the lungs.

Typically, extrapulmonary TB cases should make up the minority of TB cases (10 to 15%). Treatment regimens are generally similar, regardless of disease site; therefore, the importance of defining disease site is for surveillance purposes and to monitor program coverage of patients diagnosed and managed by specialists other than pneumologists. Extrapulmonary TB is more common among individuals coinfected with HIV; thus, a larger proportion of extrapulmonary cases may appear in areas of high HIV prevalence.

## How to Measure It

The numerator, the number of new extrapulmonary TB cases during a specified time period, can be obtained from case-finding reports at the national level. Individuals diagnosed with both pulmonary and extrapulmonary TB should not be included in the numerator. The denominator, the total number of new TB cases registered in the same period, can also be obtained from case-finding reports.

## Data Sources

- Quarterly reports on new cases and relapses of tuberculosis
- TB register

## Frequency & Function

This indicator should be measured on a quarterly and annual basis.

## Strengths & Limitations

This indicator relies on the accuracy of disease site determination at the time of diagnosis and subsequent reporting to the NTP. This indicator is useful for following trends within a country or region and for cross-country comparisons.

Indicator 2.7

# NEW TB CASES WITH NO SMEAR CONVERSION RESULT

## Definition

The percentage of new smear-positive pulmonary TB cases registered in a specified period that were not examined by sputum microscopy at the end of the initial phase of treatment.

$$\frac{\text{Number of new smear-positive pulmonary TB cases registered in a specified period that were not examined at the end of the initial phase of treatment}}{\text{Total number of new smear-positive pulmonary TB cases registered during the same period}} \times 100$$

## What It Measures

Sputum smear conversion after 2 or 3 months of treatment is a good predictor of eventual cure if treatment is completed. This indicator also has treatment implications—in some countries, patients who have not converted their sputum smear after 2 months of treatment should extend the initial phase of therapy for 1 month. Lack of evaluation of the bacteriological (microscopy) status at 2 months impedes the decision to extend the initial phase of treatment; lack of evaluation at 2 or 3 months indicates poor staff compliance with the guidelines and/or loss of patients (through default, transfer, or death) during the initial phase.

## How to Measure It

The numerator is the number of new smear-positive pulmonary TB cases registered in a specified period with no sputum results at the end of the initial phase of treatment (2 or 3 months). The denominator is the total number of new smear-positive pulmonary TB cases registered for treatment during the same period.

## Data Sources

- Quarterly reports on smear conversion or program management
- TB register

## Frequency & Function

This indicator should be collected on a quarterly and annual basis.

## Strengths & Limitations

If there are high levels of patients not evaluated, further investigation is required to determine the reason for this. For example, sputa may not have been collected, reflecting poor staff procedures or loss of patients; the results may not have been returned from the laboratory; or they may not have been registered.

**Indicator 2.8**

# SPUTUM CONVERSION RATE AT THE END OF THE INITIAL PHASE OF TREATMENT

## Definition

The percentage of new smear-positive pulmonary TB cases registered in a specified period that converted to smear negative at the end of the initial phase of treatment. The initial phase of treatment may be 2 to 3 months depending on national guidelines.

$$\frac{\text{Number of new smear-positive pulmonary TB cases registered in a specified period that are smear negative at the end of the initial phase of treatment}}{\text{Total number of new smear-positive pulmonary TB cases registered for treatment in the same period}} \times 100$$

The same definition is used to calculate sputum conversion rate among other case types (e.g., relapse cases, retreatment-after-failure cases, treatment-after-default cases).

## What It Measures

The majority of new smear-positive pulmonary TB patients should convert their smear to negative after 2 or 3 months of treatment. However, at 2 months, good laboratory technicians can often detect low grades of positivity, and the positivity rate can still be as high as 25%, even if the initial phase of treatment is well supervised and the drugs are of good quality. If adherence to treatment is poor or if sputum is not collected at the end of the initial phase, this indicator will be low. Other reasons for a low value could be a slow rate of progress with smear conversion because of extensive cavitation and a heavy initial bacillary load or, rarely, drug resistance that does not respond to first-line therapy. Sputum conversion has treatment implications since, in some countries, patients who have not converted their sputum smears after 2 months of treatment should extend the initial phase of therapy. Low rates of smear conversion after the initial phase of treatment among retreatment patients are an indication of possible drug resistance.

## How to Measure It

The numerator is the number of new smear-positive pulmonary TB cases registered in a specified period (e.g., quarter or year) that had at least one negative smear result at the end of 2 or 3 months of treatment (initial phase). This number can be obtained from the quarterly report on smear conversion (or program management) or from the TB register. The denominator is the total number of new smear-positive pulmonary TB

cases registered for treatment during the same period, and this number can be obtained from the same sources.

### Data Sources

- Quarterly reports on smear conversion
- TB register

### Frequency & Function

This indicator should be monitored on a quarterly and annual basis.

### Strengths & Limitations

This indicator relies on the capacity of the program staff to obtain sputa from patients at 2 and 3 months and the ability of the laboratories to provide accurate and complete results to the treatment centers. This indicator is useful for following trends within a country or region and for comparison between centers. Some of the patients who are still sputum smear positive at 2 or 3 months may be culture negative and already cured; this is an operational indicator, not a technical one.

**Indicator 2.9**

# CURE RATE

## Definition

The percentage of TB cases that were registered in a specified period and were cured. All TB cases recorded as cured must have a negative sputum smear result recorded during the last month of treatment and on at least one previous occasion during treatment. For the cohort of new smear-positive pulmonary TB cases, the definition is as follows:

$$\frac{\text{Number of new smear-positive pulmonary TB cases registered in a specified period that were cured}}{\text{Total number of new smear-positive pulmonary TB cases registered in the same period}} \times 100$$

The same definition is used to calculate cure among other cohorts (or case types) (e.g., relapse cases, retreatment-after-failure cases, treatment-after-default cases).

## What It Measures

Evaluation of treatment outcomes of patients is used to determine NTP quality and effectiveness. WHO has recommended that NTPs achieve at least 85% treatment success (defined as the proportion of registered patients who were cured plus the proportion who completed treatment) in order to curtail the TB epidemic (Indicator 1.3). Cured patients are the preferable contribution to the numerator of treatment success.

## How to Measure It

At the end of the treatment course, each sputum smear-positive TB case has a treatment outcome, which is recorded in the TB register. The numerator for this indicator is the number of cases registered in a specified period (e.g., quarter or year) and assigned the treatment outcome "cured." The denominator is the number of new smear-positive cases registered in the same period.

## Data Sources

- Quarterly reports on treatment outcomes
- TB register

## Frequency & Function

This indicator should be collected on a quarterly and annual basis.

## Strengths & Limitations

Sputum smear-negative results obtained at the end of treatment and once during treatment may hide a small proportion of patients who are culture positive and therefore not really cured.

Since HIV-associated TB is more likely to result in death, it is difficult to achieve a high proportion of cures in areas with high HIV prevalence. Additionally, in countries where D.O.T. is administered only in the initial phase, it may be challenging to obtain sputum during the last month of treatment, which can decrease the numerator. Likewise, where rifampicin is used throughout the continuation phase, it may be difficult to get a sputum sample, so cure rates may be low in countries that have adopted this treatment strategy. These factors should be considered when interpreting the value of the proportion cured during a specified time period.

Cohort analysis of treatment outcomes is a major management tool for evaluating the effectiveness of the NTP. These indicators rely on the accuracy of treatment outcome determination and subsequent reporting to the NTP. These indicators are useful for following trends within a country or region and for cross-country comparisons, and they can be used to monitor and evaluate the impact of specific interventions.

**Indicator 2.10**

# TREATMENT COMPLETION RATE

## Definition

The percentage of TB cases registered in a specified period that completed treatment. For new smear-positive pulmonary cases, the definition is as follows:

$$\frac{\text{Number of new smear-positive pulmonary TB cases registered in a specified period that completed treatment and did not meet the criteria for cure or failure}}{\text{Total number of new smear-positive pulmonary TB cases registered in the same period}} \times 100$$

The same definition is used to calculate outcome among other cohorts (or case types) (e.g., new smear-negative cases, relapse cases, retreatment-after-failure cases, treatment-after-default cases).

## What It Measures

Evaluation of treatment outcomes of new pulmonary smear-positive patients is used to determine NTP quality and effectiveness. This indicator measures the success of the NTP in ensuring that TB patients who cannot be classified as cured actually complete their course of treatment. Patients who have completed their treatment but do not meet the criteria to be classified as a cure or failure are designated as "treatment complete."

This indicator should be examined in conjunction with the other treatment outcome indicators. When cure cannot be established, treatment completion is the best means of ensuring that patients have been adequately treated. However, cure is always a preferable outcome to treatment completion. Treatment completion may obscure the fact that the patient is still or again smear positive and therefore is a treatment failure.

## How to Measure It

At the end of the treatment course, each sputum smear-positive TB case has a treatment outcome, which is recorded in the TB register. The numerator for this indicator is the number of cases registered in a specified period (e.g., quarter or year) and assigned the treatment outcome "treatment complete." The denominator is the number of new smear-positive cases registered in the same period.

## Data Sources

- Quarterly reports on treatment outcomes
- TB register

## Frequency & Function

This indicator should be measured quarterly and annually.

## Strengths & Limitations

Cohort analysis of treatment outcomes is a major management tool for evaluating the effectiveness of the NTP. These indicators rely on the accuracy of treatment outcome determination and subsequent reporting to the NTP. These indicators are useful for following trends within a country or region and for cross-country comparisons and can be used to monitor and evaluate the impact of specific interventions.

**Indicator 2.11**

# DEATH RATE

## Definition

The percentage of TB cases registered in a specified period that died during treatment, irrespective of cause. For new smear-positive pulmonary TB cases, the definition is as follows:

$$\frac{\text{Number of new smear-positive pulmonary TB cases registered in a specified period that died during treatment, irrespective of cause}}{\text{Total number of new smear-positive pulmonary TB cases registered in the same period}} \times 100$$

The same definition is used to calculate outcome among other cohorts (or case types) (e.g., new smear-negative cases, relapse cases, retreatment-after-failure cases, treatment-after-default cases).

## What It Measures

Evaluation of treatment outcomes of patients is used to determine NTP quality and effectiveness. Patients who died for any reason during their course of treatment are designated as "died." Cause of death is not further specified (e.g., death due to TB versus other) in the basic reporting of treatment outcomes. For this reason—and because some unknown number of patients are lost because of death—the death rate from cohort analysis is not necessarily representative of the case fatality rate.

This indicator should be considered in the context of HIV prevalence, since a high proportion of HIV-associated TB will result in a greater number of deaths. In addition to coinfection with HIV, deaths during treatment may be a result of ineffective treatment or an advanced, severe state of TB at the time treatment is initiated. In situations where people do not seek care early, there may be a high number of TB deaths that are never recorded because a large number of individuals die before being diagnosed and starting treatment. In low-prevalence countries, deaths during treatment may be due to the advanced age of the patients. In the event of excess TB mortality (more than 5%) in areas of low HIV prevalence, deaths of patients should be reviewed to determine whether these deaths could have been prevented and/or whether programmatic interventions are warranted.

## How to Measure It

At the end of the treatment course, each smear-positive pulmonary TB case has a treatment outcome, which is recorded in the TB register. The numerator for this indicator is the number of cases registered in a specified period (e.g., quarter or year) and assigned the treatment outcome "died." The denominator is the number of new smear-positive cases registered in the same period.

## Data Sources

- Quarterly reports on treatment outcomes
- TB register

## Frequency & Function

This indicator should be collected on a quarterly and annual basis.

## Strengths & Limitations

Cohort analysis of treatment outcomes is a major management tool for evaluating the effectiveness of the NTP. These indicators rely on the accuracy of treatment outcome determination and subsequent reporting to the NTP. These indicators are useful for following trends within a country or region and for cross-country comparisons, and they can be used to monitor and evaluate the impact of specific interventions. This indicator includes patients who died for any reason during TB treatment; therefore, there may be related factors that can affect this calculation, in particular, HIV/AIDS. On the other hand, some deaths may not be reported and may be falsely counted as lost to follow-up.

**Indicator 2.12**

# TREATMENT FAILURE RATE

## Definition

The percentage of TB cases registered in a specified period that were treatment failures. For new smear-positive pulmonary TB cases, the definition is as follows:

$$\frac{\text{Number of new smear-positive pulmonary TB cases registered in a specified period that are smear positive 5 months or later after initiating treatment}}{\text{Total number of new smear-positive pulmonary TB cases registered in the same period}} \times 100$$

## What It Measures

Evaluation of treatment outcomes of new pulmonary smear-positive patients is used to determine NTP quality and effectiveness. This indicator measures one of the possible outcome indicators for patients. Patients who are sputum smear positive at 5 months or later during the course of treatment are designated as "treatment failure."

Treatment failure may be due to inappropriate treatment regimens or underlying primary resistance. If the number is too low, this indicates a measurement problem. No NTP can achieve a 0% treatment failure rate, but the goal is to attain the lowest failure rate possible. When treatment failure rates exceed 3%, case management should be reviewed to determine whether these failures could have been prevented and/or whether program interventions are warranted.

## How to Measure It

At the end of the treatment course, each smear-positive pulmonary TB case has a treatment outcome, which is recorded in the TB register. The numerator for this indicator is the number of cases registered in a specified period (e.g., quarter or year) and assigned the treatment outcome "treatment failure" after the last control smear is taken and the results are recorded. The denominator is the number of new smear-positive cases registered in the same period.

## Data Sources

- Quarterly reports on treatment outcomes
- TB register

## Frequency & Function

This indicator should be collected on a quarterly and annual basis.

## Strengths & Limitations

Cohort analysis of treatment outcomes is a major management tool for evaluating the effectiveness of the NTP. These indicators rely on the accuracy of treatment outcome determination and subsequent reporting to the NTP. These indicators are useful for following trends within a country or region and for cross-country comparisons, and they can be used to monitor and evaluate the impact of specific interventions.

**Indicator 2.13**

# DEFAULT RATE

## Definition

The percentage of TB cases registered in a specified period that interrupted treatment for more than 2 consecutive months. For new smear-positive pulmonary TB cases, the definition is as follows:

$$\frac{\text{Number of new smear-positive pulmonary TB cases registered in a specified period that interrupted treatment for more than 2 consecutive months}}{\text{Total number of new smear-positive pulmonary TB cases registered in the same period}} \times 100$$

The same definition is used to calculate outcome among other cohorts (or case types) (e.g., new smear-negative cases, relapse cases, retreatment-after-failure cases, treatment-after-default cases).

## What It Measures

Evaluation of treatment outcomes of patients is used to determine NTP quality and effectiveness. This indicator is one of the possible outcome indicators for patients. Patients whose treatment was interrupted for 2 or more consecutive months (e.g., patients who did not collect drugs for 2 or more months at any time after registration) are designated as "default." Any default should prompt further investigation to determine whether the interruption could have been prevented and/or whether program interventions are warranted. It is very difficult to achieve a default rate of less than 2 or 3%. If the default rate is high (i.e., more than 15%), the success target of 85% is not achievable, and the causes of this defaulting need to be determined in order to take remedial action.

## How to Measure It

At the end of the treatment course, each sputum smear-positive TB case has a treatment outcome, which is recorded in the TB register. The numerator for this indicator is the number of cases registered in a specified period (e.g., quarter or year) and assigned the treatment outcome "default." The denominator is the number of new smear-positive cases registered in the same period.

## Data Sources

- Quarterly reports on treatment outcomes
- TB register

## Frequency & Function

This indicator should be collected on a quarterly and annual basis.

## Strengths & Limitations

Cohort analysis of treatment outcomes is a major management tool for evaluating the effectiveness of the NTP. These indicators rely on the accuracy of treatment outcome determination and subsequent reporting to the NTP. These indicators are useful for following trends within a country or region and for cross-country comparisons, and they can be used to monitor and evaluate the impact of specific interventions. This indicator does not provide any information about when or why a patient has defaulted, and therefore comparisons between regions or countries may yield invalid conclusions.

**Indicator 2.14**

# TRANSFER-OUT RATE

## Definition

The percentage of TB cases registered in a specified period that were transferred to another basic management unit from which there is no treatment outcome information. For new smear-positive pulmonary TB cases, the definition is as follows:

$$\frac{\text{Number of new smear-positive pulmonary TB cases registered in a specified period that were transferred to another basic management unit and for which there is no treatment outcome information}}{\text{Total number of new smear-positive pulmonary TB cases registered during the same period}} \times 100$$

The same definition is used to calculate outcome among other cohorts (or case types) (e.g., new smear-negative cases, relapse cases, retreatment-after-failure cases, treatment-after-default cases).

## What It Measures

Evaluation of treatment outcomes of patients is used to determine NTP quality and effectiveness. This indicator is one of the possible outcome indicators for patients. Patients who have been transferred to another reporting unit and for whom the treatment outcome is not known are designated as "transfer out." Otherwise, transferring cases should normally have one of the other treatment outcomes. In the event of high transfer-out rates (greater than 3 or 4%), further investigation should be conducted to determine why the true outcomes are not being obtained and reported.

## How to Measure It

At the end of the treatment course, each sputum smear-positive TB case is assigned a treatment outcome, which is recorded in the TB register. The numerator for this indicator is the number of cases registered in a specified period (e.g., quarter or year) and assigned the treatment outcome "transfer out." The denominator is the number of new smear-positive cases registered in the same period.

## Data Sources

- Quarterly reports on treatment outcomes
- TB register

## Frequency & Function

This indicator should be collected on a quarterly and annual basis.

## Strengths & Limitations

If the number of transfer-out cases is remarkably large, it may mean that:

- Transfer of care is such a common reality in this setting, and for a fairly large percentage of the transferring patients, the outcome is unknown.
- Transfer out includes a high proportion of patients who have actually defaulted but have been incorrectly evaluated as "transfer out."

Transfer of care is not an event to be avoided. Patients should be accommodated by the program. A high rate of "transfer out" is really an indication of the quality of communication among health services units. It may be expected that a few very rare instances of transfer simply cannot be followed up (e.g., transfer out of the country).

Cohort analysis of treatment outcomes is a major management tool for evaluating the effectiveness of the NTP. These indicators rely on the accuracy of treatment outcome determination and subsequent reporting to the NTP. These indicators are useful for following trends within a country or region and for cross-country comparisons, and they can be used to monitor and evaluate the impact of specific interventions.

**Indicator 2.15**

# RETREATMENT FAILURE RATE (CHRONIC TB RATE)

## Definition

Percentage of retreatment (treatment-after-failure, treatment-after-relapse, and treatment-after-default) sputum smear-positive pulmonary cases registered during a specified period that are smear positive at the end of the retreatment regimen.

$$\frac{\text{Number of retreatment smear-positive pulmonary TB cases registered in a specified period that are smear positive at the end of the retreatment regimen}}{\text{Total number of retreatment smear-positive pulmonary TB cases registered in the same period}} \times 100$$

## What It Measures

Retreatment failure is an important indicator of possible drug-resistant strains in the community, which should be confirmed by the drug resistance surveillance. This indicator measures one of the possible outcome indicators for patients. Patients who are still sputum smear positive at the end of the retreatment regimen are designated as "chronics" and are noted as "treatment failure" in the TB register and in the quarterly report on treatment outcomes. The indicator is useful for program decisions regarding the adoption of treatment with second-line drugs. Treatment failure may be due to inappropriate treatment regimens underlying primary or secondary resistance, inadequate retreatment regimens, or misclassification of chronic patients.

## How to Measure It

At the end of the treatment course, each smear-positive pulmonary TB case is assigned a treatment outcome, which is recorded in the TB register. The numerator for this indicator is the number of retreatment cases registered in a specified period (e.g., quarter) and assigned the treatment outcome "treatment failure" after the last control smear is taken and the results are recorded. The numerator and denominator can be obtained from the TB register. This indicator is reported routinely from district level upwards.

## Data Source

- TB register

## Frequency & Function

This indicator should be collected on a quarterly and annual basis.

## Strengths & Limitations

Cohort analysis of treatment outcomes is a major management tool for evaluating the effectiveness of the NTP. These indicators rely on the accuracy of treatment outcome determination and subsequent reporting to the NTP. These indicators are useful for following trends within a country or region and for cross-country comparisons, and they can be used to monitor and evaluate the impact of specific interventions. This indicator complements Indicator 2.12 for new cases.

# 3. Political Commitment

## Introduction

In TB control, political commitment is absolutely essential for scale-up, impact, and sustainability of effective interventions. Therefore, sustained political commitment is among the five core elements of the DOTS strategy. The commitment of governments to specific policies and programs is notoriously difficult to measure in a quantitative fashion, especially in complex integrated or decentralized health systems. Nevertheless, it is possible to broadly gauge whether support is strong, moderate, or weak. There are various means by which commitment can be expressed, including 1) via policy document language, 2) via plans, budgets, and financing, and 3) via institutional engagement, human resources availability, and interagency coordination. Each of these areas is covered within the list of indicators described in the following pages.

**Policies:** The first set of proposed political commitment indicators relates to the existence of approved policies that are consistent with effective DOTS delivery. These include documented statements of the priority of TB control and/or communicable disease control, expressed in the national health system and development and poverty reduction policies (Indicators 3.1 and 3.2); standardized and disseminated norms (national TB control manual) (Indicator 3.3); and a commitment to collaborative TB and HIV activities (Indicator 3.12).

**Plans, budgets, and financing:** The second set of indicators relates to the documentation of strategic plans, annual work plans, budgets, and financing to support implementation of stated policies. In countries with high TB burden, a number of key documents are needed to guide, manage, and finance effective TB control and related financial allocations, whether under highly categorical programs or under more integrated systems of health service delivery (Indicators 3.4 through 3.8).

**Institutions, human resources, and coordination:** The third set of proposed indicators concerns the documented evidence of the institutional anchor for coordinated national TB control (i.e., a central TB unit); the availability of key human resources needed to direct and manage TB control interventions; and the existence of an effective coordination mechanism among key agencies in government, the donor community, and civil society, given the technical complexity of TB control and case management (Indicators 3.9 through 3.11).

## Limitations

Good TB control performance is not dependent on one expression of political commitment alone. For example, strong policy statements committing to prioritize TB control may not always be accompanied by operational plans and budgets, or by disbursement of funds for implementation and coordination. Furthermore, the indicators provided are only proxies for political commitment and are affected by other variables as well. Therefore, no one or two indicators will adequately reflect commitment, and not all will be appropriate in any given country. A radar graph with high/low or high/medium/low gauges may be a useful way to present and reflect on multiple indicators at once.

Although absolute and relative financial investments may be among the most important measures of political commitment, they are difficult to evaluate on the basis of generic measures. Selecting a proportional measure of financial commitment that could be adopted in a majority of countries would be impossible (e.g., a percentage of gross national product per capita, a percentage of public expenditure in health, a percentage relative to other public health priorities). Such standardized proportions would lend themselves too easily to misinterpretation, given the diversity of factors (e.g., underlying epidemiological burdens, economic and political systems, income, level of donor dependency). Standardized indicator review will be less useful than qualitative assessments of domestic and international financing trends for evaluating commitment and for problem-solving.

Many of the indicators in this section are written to be measured at the national level, but they could be adapted for all levels of a health system.

## Indicators

- TB control is among stated priorities
- National TB policy
- National TB program manual
- NTP medium-term development plan and budget
- NTP annual work plan and budget
- Peripheral units with work plan and budget
- Financial resources committed to NTP from the government
- Annual NTP budget allocated to implement DOTS as required by medium-term development plan
- Key NTP staff positions filled
- Interinstitutional coordination of TB control

- Existence and dissemination of NTP annual report
- National TB control policy addresses links between TB and HIV

## Resources

*An expanded DOTS framework for effective tuberculosis control. WHO report 2002*. Geneva, World Health Organization, 2002 (WHO/CDS/TB/2002.297). (This includes a full explanation of the DOTS strategy and elements, background considerations, and application.)

Bertrand J, Escudero G. *Compendium of indicators for evaluating reproductive health programs, Vol. 1. Overview indicators that crosscut programmatic areas*. Chapel Hill, NC, Carolina Population Center, 2002 (MEASURE Evaluation Manual Series, No. 6).

*Global tuberculosis control: surveillance, planning, financing. WHO report 2003*. Geneva, World Health Organization, 2003 (WHO/CDS/TB/2003.316).

Hanson C. *Expanding DOTS in the context of a changing health system*. Geneva, World Health Organization, 2003 (WHO/CDS/TB/2003.318). (This includes important additional selected indicators that can help gauge the likely effectiveness and/or impact of health reform measures on TB control structures, effectiveness, and sustainability.)

Pinet G. *Good practice in legislation and regulations for TB control: an indicator of political will.* Geneva, World Health Organization, 2001 (WHO/CDS/TB2001.290).

**Indicator 3.1**

# TB CONTROL IS AMONG STATED PRIORITIES

## Definition

A qualitative indicator that notes whether TB control, in particular, or communicable disease control, in general, is among the stated health and development priorities of a government or, specifically, the Ministry of Health. This information is reflected in national planning documents. This is a yes/no indicator.

## What It Measures

The indicator provides a minimal indicator of government support for TB control and its integration within the array of public health, poverty reduction, or development objectives and priorities. Although TB control has risen as a priority globally and is included among the indicators of the United Nations (UN) Millennium Development Goals, there is still variability in its positioning among the large array of public health and development challenges in countries with high and moderate TB burden. National TB programs and their partners can benefit from engaging in the development, discussion, and/or tracking of large health sector, poverty reduction, and development strategies and planning documents. The existence of TB control as a stated priority does not necessarily signify strong government and partner support for TB efforts. However, the absence of any mention of TB control or communicable disease control may be a signal of important deficiencies in support for TB control and/or engagement of TB control implementers in health or development planning.

## How to Measure It

This indicator is measured via review of stated references to TB control within the major planning and strategy documents. These will vary substantially from country to country. For example, in some countries, a Planning Ministry will oversee the development of 5-year strategic plans for government investment and activity, as well as annual plans. In other settings, poverty reduction strategy papers are prepared with the assistance of development partners, including the World Bank, the International Monetary Fund, bilateral agencies, and UN agencies. MOHs develop broad sectoral plans and medium-term expenditure frameworks that provide the foundation for prioritizing and allocating the use of scarce human and financial resources.

## Data Sources

- Government planning and strategy documents

## Frequency & Function

This indicator should be monitored annually or upon release of any new major government and MOH planning and strategy documents. This indicator is measured at the national level.

## Strengths & Limitations

As noted above, this is a minimal indicator that is most useful where there may be omissions in references to TB control, when other public health challenges may be noted and addressed. There may be examples where priorities are restricted to one or two themes in the health sector (e.g., HIV/AIDS), and it may be highly appropriate that TB control is not included in this specified first tier of priorities. Where TB control is included in stated priorities, it may still not suggest that TB control is or will be well financed or supported, especially where priorities are numerous or ill defined. Review of planning and strategy documents is an important process in itself. It provides a chance to identify major themes and opportunities for linking TB control within broader concerns (e.g., targeted poverty reduction efforts, responses to urbanization, refugee challenges, penal reform, community-driven development).

**Indicator 3.2**

# NATIONAL TB POLICY

## Definition

The government formally adopts, through legislative or administrative measures, a complete national TB control policy that supports the internationally recommended DOTS strategy and guidelines for tuberculosis control. This is a yes/no indicator—either the national policy is complete or incomplete.

## What It Measures

The adoption of a formal policy demonstrates political commitment to action at the central level and facilitates more effective, strategic implementation of TB control activities. The policy should reflect the internationally accepted DOTS strategy and specify its position in the health system as a key element of health services. The policy should also refer to the role played by management units and facilities at all levels of the health system in DOTS implementation, with a goal of nationwide coverage. This indicator may be helpful for stimulating policy development and for identifying strengths and weaknesses of national TB control policy.

## How to Measure It

A content analysis of the national TB policy and guidelines should be conducted and matched against the key policy components listed below. Routine monitoring will allow for an assessment to determine which components are lacking. A policy is considered complete if it contains the following key policy components and is formally adopted by the government:

- Program goals
- Establishment of an NTP management unit
- Description of financial and human resources needed by NTP, including roles and responsibilities at all levels
- Description of the smear microscopy network and its use as the primary method for diagnosing pulmonary TB
- Administration of standardized short-course chemotherapy under direct observation
- Description of drug management as well as standardized recording and reporting systems

- ❑ The role of and approaches to the private medical sector
- ❑ Description of the involvement of other government institutions and partner organizations.

## Data Sources

- Formal MOH policies and/or directives regarding TB control at the national level
- Checklist of key policy components

## Frequency & Function

This indicator should be measured annually and used for monitoring purposes.

## Strengths & Limitations

Measurements of political commitment require some subjective evaluation; they are rarely useful for cross-national comparisons and may not capture trends. This indicator goes beyond identifying the existence of a national policy by defining components of a "complete" policy according to international guidelines. This indicator does not ensure that all components are fully funded or implemented, only that the government has articulated political commitment to them. Likewise, the quality of program goals cannot be assessed with this indicator.

**Indicator 3.3**

# NATIONAL TB PROGRAM MANUAL

## Definition

A complete manual of norms and procedures for management of DOTS programs exists and is disseminated to all diagnostic and treatment centers affiliated with the NTP. This is a yes/no indicator—either the manual is complete or incomplete.

## What It Measures

The existence of an NTP manual to guide implementation of DOTS shows that MOH is taking a step towards institutionalizing norms and procedures associated with DOTS at facilities throughout the health system. The development and dissemination of a manual requires a significant investment of time and money, which the NTP is not likely to make unless it is serious about promoting the DOTS strategy as the national norm for TB control.

## How to Measure It

The NTP manual should be oriented towards implementing DOTS, as described in the national TB policy (Indicator 3.2). The manual contents should be analyzed and compared with the components listed below. Thus, at a minimum, the following components should be addressed in terms of how they are operationalized through the NTP:

- Program goals
- Establishment of an NTP management unit
- Description of human resources needed by NTP
- Promotion of smear microscopy as primary method for diagnosing pulmonary TB
- Administration of standardized short-course chemotherapy, consistent with WHO recommendations, under direct observation
- Description of drug management system
- Description of standardized recording and reporting system, according to international guidelines
- Roles and responsibilities at different levels
- TB and HIV collaboration.

## Data Sources

- Manual of norms and procedures for NTPs
- Checklist of key manual components

## Frequency & Function

This indicator should be monitored annually to check whether or not the guidelines for program implementation are appropriate, given the ongoing expansion of DOTS programs in terms of geographic coverage and mandate.

## Strengths & Limitations

Similar to other political commitment indicators, the existence of a manual for DOTS implementation does not ensure that the guidelines are used in the everyday practice of TB control at the facility level. This could be due to a lack of training in specific procedures or resistance to change on the part of doctors and other clinicians who are charged with the clinical management of TB. However, without a manual, the NTP has no central reference or resource for program managers who need information on norms and procedures.

Indicator 3.4

# NTP MEDIUM-TERM DEVELOPMENT PLAN AND BUDGET

## Definition

A complete medium-term development plan and budget, consistent with international guidelines, directs NTP activities over a 3- to 5-year period. This is a yes/no indicator—the MDP and related budget are either complete or incomplete according to international and country guidelines.

## What It Measures

This indicator measures the ability of the NTP to strategically plan and budget for activities aimed at achieving global targets for TB control. The MDP highlights country needs and resource gaps, emphasizing collaboration among key local, national, and international agencies involved in TB control. The MDP should also reinforce government commitment and be used to mobilize national and external resources. Increasingly, governments (e.g., Ghana, Uganda, United Republic of Tanzania) are developing strong frameworks for medium-term planning in the health sector as a whole and providing parameters for disease- or program-specific plans.

## How to Measure It

The MDP and budget contents should be analyzed and compared with the key MDP components listed below. The MDP framework may vary from country to country and should not only be consistent with international guidelines, but also with national health sector guidelines for programmatic development plans. In countries where sectorwide planning is occurring, the NTP MDP and budget may fall within sectorwide planning and not as a separate document. In a decentralized system, components may appear at the regional or district level; however, the NTP should provide advocacy and technical support for these areas in its work plan. The design of decentralized plans may depend on local MOH guidelines. The MDP should reflect all components included in a complete national policy (Indicator 3.2), as well as the following additional components:

**Medium-term development plan**

- ❑ Situation analysis
- ❑ Clear goals and measurable objectives that support the NTP policy, with indicators defined for each goal and objective
- ❑ Strategies to meet NTP objectives, including:

  - ❑ DOTS components: political commitment; case detection; case management (including D.O.T.); drug supply; recording and reporting system; and human resources development, supervision, and health systems
  - ❑ Specific initiatives to improve or broaden DOTS: examples include TB and HIV collaborative activities, MDR-TB/DOTS-Plus, public and private mix, infection control, operations research, community-based DOTS, social mobilization/IEC, and prison-based initiatives
- ❑ Activities to support program goals and objectives
- ❑ Monitoring and evaluation of national TB program implementation
- ❑ A timeframe.

**MDP budget**

- ❑ Budget defined for each DOTS component
- ❑ Budget defined for each specific initiative to improve or broaden DOTS
- ❑ Budget tables showing both the total budget and a detailed breakdown by line item (e.g., each DOTS component, each specific initiative) and funding source (e.g., government, WHO, World Bank loan, USAID, GFATM)
- ❑ Harmonization of donor funding and general roles and responsibilities of partners.

## Data Sources

- NTP MDP and budget

## Frequency & Function

This indicator should be measured as a monitoring indicator every 2 to 3 years to detect any revisions that may be made during implementation and to provide an overall strategic context for other activities that are reviewed more frequently.

## Strengths & Limitations

The measurement of the MDP and budget alone is not a measure of quality or whether the NTP can implement the MDP given political, financial, or epidemiological realities. Furthermore, in the context of a decentralized NTP, the plan and budget may not necessarily translate into action at the district level.

In countries that develop a framework for medium-term planning in the health sector as a whole and provide parameters for disease- or program-specific plans, it is important for the NTPs to work with partners in MOH to develop these sectorwide plans, seek endorsements of them, and ensure that their objectives, major strategies, and results are incorporated into larger synthesis planning and reporting documents.

**Indicator 3.5**

# NTP ANNUAL WORK PLAN AND BUDGET

## Definition

A complete annual plan and budget, consistent with international guidelines and the MDP, that describes the NTP activities to be undertaken in a specific year, the budget for these activities, and the sources of funding for these activities. This is a yes/no indicator—the plan and budget are either complete or incomplete.

## What It Measures

This indicator measures the ability of the NTP to translate its MDP into a detailed annual plan and budget. In a decentralized system, annual plans and budgets may also be produced at the regional or district level.

## How to Measure It

The contents of the annual plan and budget should be analyzed and compared with the key components listed below. In countries where sectorwide planning is occurring, the NTP annual work plan and budget may fall within this framework and not as a separate document. The plan should be consistent with national policy (Indicator 3.2) and the MDP (Indicator 3.4) and should include, at the minimum, the following components:

**Key components: annual plan of activities**

- ❑ Detailed list of activities for each objective defined in the MDP
- ❑ Timeframe for each activity
- ❑ Definition of the person(s) or agency responsible for implementation of each activity
- ❑ Definition of the indicators to be used to assess whether or not activities were successfully implemented
- ❑ Definition of the budget required for each activity, whether or not activities were successfully implemented
- ❑ Description of the source of funding for each activity.

**Key components: annual budget**

- ❑ There should be a table summarizing the budget required for the annual plan of activities. This should include the total budget requirements and a breakdown of the budget by line item (e.g., each component of DOTS, any specific initiative designed to improve or broaden DOTS) and funding source (e.g., government, WHO, World Bank, USAID, GFATM).

## Data Sources

- NTP annual plan and budget
- MDP

## Frequency & Function

This indicator should be measured annually and routinely used as a monitoring indicator.

## Strengths & Limitations

Assessment of the annual work plan and budget alone cannot measure successful implementation or whether the planned activities and budget will be sufficient to achieve MDP objectives. Furthermore, in the context of a decentralized NTP, the plan and budget may not necessarily translate into action at the district level.

**Indicator 3.6**

# PERIPHERAL UNITS WITH WORK PLAN AND BUDGET

## Definition

In a decentralized system, the percentage of peripheral management units (e.g., regional and district offices) with budget responsibility for which a complete annual work plan and budget consistent with international guidelines and the MDP are available.

$$\frac{\text{Number of peripheral management units for which a work plan and budget are available}}{\text{Total number of peripheral management units with budget and planning responsibility}} \times 100$$

## What It Measures

This indicator measures the planning capacity of peripheral management units in a decentralized health system. Thus, it provides information on how well the NTP is organized at the subnational level. Decentralization is a relatively new concept for many countries, and a lack of managerial experience at peripheral units impedes the effective implementation of NTP policy. All decentralized NTPs should aim to reach 100% on this indicator. It should be used as an internal indicator for the NTP and validated during an external monitoring activity.

## How to Measure It

Determination of the numerator and denominator will depend on whether or not peripheral management units are required to submit annual work plans and budgets to the central NTP management office. Where these units submit the items to the central office, the numerator is the number of units that submitted a complete work plan and budget to the NTP for the current fiscal year, and the denominator is the total number of units required to submit plans to the central level. Where the work plan and budget remain at the peripheral level, the numerator is the number of units included in the current M&E activity that have a work plan and budget, and the denominator is the total number of units included in the M&E activity. Regardless of the method, each work plan and budget should be reviewed with the list of key components for work plans and budgets included in Indicator 3.5.

## Data Sources

- Work plans and budgets available at the central level or at peripheral units
- Checklist of key components for annual work plans (Indicator 3.5)

## Frequency & Function

This indicator should be measured annually and used as a monitoring indicator, especially in countries that are currently decentralizing management of the health sector.

## Strengths & Limitations

The measurement of the annual work plan and budget alone is not a measure of quality or whether the NTP can implement the plan given political, financial, or epidemiological realities. Additionally, the plan is not meant to provide details on activities nor serve as an indicator of the adequacy of resources committed to each component. TB activities may not have the same priority at the district level as at the national level, given the smaller population and number of TB cases; TB activities and budget may be part of communicable diseases or a general PHC system and not identified specifically.

**Indicator 3.7**

# FINANCIAL RESOURCES COMMITTED TO NTP FROM THE GOVERNMENT

## Definition

The percentage of the NTP budget, as defined in the MDP or annual plan of activities, that is funded by the national government.

$$\frac{\text{Total funding from the national government for the annual plan of activities}}{\text{Total budget required for full implementation of the annual plan of activities (consistent with MDP)}} \times 100$$

## What It Measures

This indicator measures the national government's level of financial commitment to TB control.

## How to Measure It

Data on available funding should be compiled and compared with the budget defined in the annual plan of activities.

## Data Sources

- Annual TB work plan and budget
- MDP budget

## Frequency & Function

This indicator should be measured annually and used as a monitoring indicator.

## Strengths & Limitations

The components of the NTP budget must remain fairly consistent in order to make comparisons over time. A more general limitation of this indicator is that most existing budgets do not cover the costs of resources that are essential for TB control but that are shared by TB programs and other programs and services (e.g., general health services, staff, buildings). These resources are usually funded primarily by the national government, but they are not measured in this indicator. As a result, the indicator may underestimate the total contribution of the national government to TB control, as well as the overall fraction of total TB control costs that are funded by the national government.

**Indicator 3.8**

# ANNUAL NTP BUDGET ALLOCATED TO IMPLEMENT DOTS AS REQUIRED BY MEDIUM-TERM DEVELOPMENT PLAN

## Definition

Total amount of funds (all sources) available to NTP for DOTS-based TB control, as a percentage of the annual amount specified by the MDP for DOTS implementation and related activities.

$$\frac{\text{Total amount of funds allocated for DOTS-based TB control in the previous year's NTP budget}}{\text{Total amount of funds budgeted for DOTS-based TB control in the previous year's NTP budget as described in the annual plan}} \times 100$$

## What It Measures

This indicator demonstrates progress made by the NTP in securing funds for implementation of DOTS and identifies important funding gaps that will need to be filled by government, donors, or both in order to make progress in global TB control. The proportion of funds needed that is annually available is also a check on whether or not goals and objectives in the MDP are realistic and sustainable over the 3- to 5-year planning period.

## How to Measure It

The numerator is the amount of funds from all sources that were allocated for TB control in the annual work plan or MDP for the previous year. The denominator is the corresponding annual figure budgeted for the annual work plan or MDP.

## Data Sources

- Annual NTP work plan and budget
- MDP budget

## Frequency & Function

This indicator should be measured annually and used as a monitoring indicator.

## Strengths & Limitations

As with other financial indicators, the components of the NTP budget must remain fairly consistent for comparisons to be made over time. A more general limitation of this indicator is that most existing budgets focus on costs specific to TB control. They do not include an assessment of costs to the general health system (e.g., for staff and buildings that are shared among different types of patients and are required with or without a TB control program). These resources are essential for successful TB control but are not necessarily measured in this indicator. The indicator may also be used to determine whether or not funding levels are appropriate for specific DOTS components and activities, especially if a DOTS-Plus pilot or another costly program is introduced.

**Indicator 3.9**

# KEY NTP STAFF POSITIONS FILLED

## Definition

The percentage of key NTP positions filled by local staff, according to MDP.

$$\frac{\text{Number of key NTP positions filled by local staff}}{\text{Total number of key NTP positions, as described in the NTP human resources development plan}} \times 100$$

## What It Measures

This indicator measures political commitment to TB control in terms of human resources and provides information on the organizational and human resources capacity to perform and achieve the objectives outlined in the MDP. Specifically, the NTP requires a combination of employees possessing skills in clinical management, laboratory expertise, data management, drug procurement and distribution, training, and supervision. Some NTPs will meet staffing needs through a unique combination of employees possessing the necessary skills to manage the program. This may include full-time staff in some areas of program management and part-time staff who are "shared" with other programs, as is common in NTPs that combine their efforts with leprosy programs or are part of a larger communicable diseases office.

## How to Measure It

Staff positions included in the numerator and denominator should include managerial staff; clinical staff employed at the service delivery level are not included. Technical advisors supported by donors should not be included in the assessment of optimum staffing levels, and the contribution of part-time staff working on other infectious disease programs must be considered in light of the TB situation in a given country.

A program could be considered fully staffed if the following key areas are covered by a combination of staff who work full- or part-time for the NTP, according to the human resources development plan (if available).

| National Level | Regional Level | District Level |
|---|---|---|
| • Overall TB program management<br>• TB laboratory management<br>• Drug management<br>• Human resources development<br>• M&E<br>• Research | • Coordination of TB control activities<br>• Laboratory management | • Coordination of TB control activities<br>• Laboratory management |

Depending on the epidemiological situation, country size, TB burden, and TB program activities, specific staff may be necessary at the national level or for programs for TB/HIV, MDR-TB, and social mobilization/IEC.

## Data Sources

- NTP organizational diagram, with clearly assigned staff positions and their functions
- Human resource development plan

## Frequency & Function

This indicator should be measured annually because of staff turnover and changes due to disease burden (other than TB) or other MOH priorities beyond the control of the NTP.

## Strengths & Limitations

This indicator can only provide a "snapshot" of the human resources situation at one point in time. One important limitation of this indicator is that it does not measure competency of the staff filling key positions. Second, if the program has local staff whose salaries are subsidized by donors, the NTP is not as committed to providing human resources as an NTP where all staff salaries are covered by the government budget. Another limitation is that the denominator is the number of key positions described in the human resources development plan. If this plan is not well developed to fit the TB situation in the country, the indicator loses its value.

**Indicator 3.10**

# INTERINSTITUTIONAL COORDINATION OF TB CONTROL

## Definition

Existence of an interinstitutional coordinating body consisting of key agencies and institutions, of the public and private sectors, that participate in a formal process of planning, implementation, and funding of TB control. This is a yes/no indicator.

## What It Measures

This indicator demonstrates commitment to a comprehensive and multisectoral approach to TB control. Depending on the country, there are a variety of agencies involved with TB control, and these will be specific to the context. Examples include MOH, Ministry of Justice, Ministry of Interior, national AIDS control program (NACP), private sector health care associations, and NGOs. Ideally, all agencies implementing TB control activities should be coordinated through a national TB advisory committee or task force, and specific referral systems, for example, between the prison and civilian TB systems, should be established. In some countries, the concept of a Stop TB partnership is being established at the country level.

## How to Measure It

There are three basic components to this indicator, and each country program should be scored yes/no on the basis of the evidence of the components:

- Evidence of regular coordination among and communication between key partners (e.g., meeting reports)
- Evidence of standardized recording and reporting to the NTP (e.g., review of reporting forms)
- Evidence that all key agencies involved in TB control follow NTP guidelines.

This indicator is measured at the national level; however, participation in these activities by local or regional associations or NGOs involved with TB control should be documented and encouraged.

## Data Sources

- Reports from coordination meetings
- Joint planning documents, if available
- Recording and reporting forms

## Frequency & Function

This indicator should be measured annually as a monitoring indicator for tracking organizational involvement in TB control.

## Strengths & Limitations

This indicator is not useful for cross-country comparisons because of its subjective nature. Measuring the contribution of key agencies may be problematic. For example, if two agencies are working together and achieve the three components but do not include a third agency managing a significant part of the TB burden in the country, the indicator will lose its value. Additionally, where the NTP has decentralized planning and implementation at the regional or district level, there may be local organizations that are involved with TB control activities but are not represented at the central level, so their presence and coordination with other local actors should be considered.

**Indicator 3.11**

# EXISTENCE AND DISSEMINATION OF NTP ANNUAL REPORT

## Definition

A complete report on NTP outcomes and activities is produced and disseminated annually. This is a yes/no indicator.

## What It Measures

The existence of an annual report allows the NTP, MOH, donors, and other interested parties to track yearly progress in DOTS implementation and shows the capacity of the NTP to compile data, report on key indicators, and assess general strengths and weaknesses of the DOTS program. The production of a basic annual report also demonstrates accountability to MOH and donors.

## How to Measure It

The report should correspond to priorities and objectives identified in the annual work plan; report the outcomes of key activities of the program, including cohort analysis outcomes and results of global and program indicators; analyze NTP challenges; and specify next steps to address these concerns. Additionally, it should be disseminated to all levels of the program and to the partners identified in Indicator 3.10. If countries are required by MOH to report on priority programs (including TB) in a standardized format, this report is sufficient.

## Data Sources

- NTP annual reports
- Dissemination records

## Frequency & Function

This indicator should be measured annually.

## Strengths & Limitations

The key limitation of this indicator is that the development and existence of an annual report do not ensure that it has correctly identified programmatic strengths and weaknesses, nor that it is used for future program planning and management.

**Indicator 3.12**

# NATIONAL TB CONTROL POLICY ADDRESSES LINKS BETWEEN TB AND HIV

## Definition

National TB control policy, endorsed by government, addresses the link between TB and HIV, and the potential impact that HIV may have on TB control throughout the country. This is a yes/no indicator—either the national policy is complete or incomplete.

## What It Measures

This indicator measures government commitment to TB and HIV collaboration by evaluating whether government TB policy assesses and addresses the potential impact that HIV may have on TB control. A national TB control policy is an official government statement that establishes goals for TB control, includes strategies for attaining them, and guides implementation of a comprehensive TB control program. The potential impact of HIV on TB control is so great that it is considered essential that governments accept the link between TB and HIV and explicitly address, within the national TB control policy, the likely impact of HIV on TB control in their setting.

## How to Measure It

National TB control policy should reflect international policy guidance on collaborative TB and HIV activities. A content analysis of the government's TB policies, plans, and/or guidelines should be conducted and matched against the key policy components listed below. A policy is considered complete if it contains all of the following eight key components:

- Explicit recognition of the potential impact of HIV on TB control
- Inclusion of NACP representative in the planning process of the NTP
- Surveillance of HIV prevalence among TB patients that is consistent with international recommendations
- IEC strategy for TB that includes appropriate information about HIV
- Training for those working in TB that includes appropriate information about HIV
- Recommendation of intensified TB case-finding for all who test positive for HIV
- Eligibility of HIV-infected TB patients for antiretroviral therapy as indicated by national protocols
- Full access to the continuum of care for people living with HIV/AIDS (PLWHA) granted to TB patients who are infected with HIV.

Additional components are required for countries with a generalized HIV epidemic (more than 1% in the general population):

- ❑ Establishment of a national TB and HIV coordinating body, technical advisory committee, or task force
- ❑ HIV testing and counseling that are routinely offered to all patients diagnosed with TB
- ❑ Availability of cotrimoxazole preventive therapy for all HIV-positive TB patients and PLWHA consistent with international guidelines.

Supporting documentation should include the policy, plan, or guideline itself, as well as where or by whom it was issued or published.

### Data Sources

- Policy audit of MOH and NTP records and policies
- Checklist of key components for policy

### Frequency & Function

This indicator should be measured at the national level every 3 to 5 years if complete or annually if not complete.

### Strengths & Limitations

Measuring political commitment and policy analysis involves some subjective judgment and limits use in cross-national comparisons, and it may not capture trends over time. This indicator goes beyond measuring the simple existence of a TB prevention and control policy by defining standards that must be met in order to have a "complete" policy that addresses the issue of HIV according to international guidelines, thus eliminating some, though not all, subjective judgment. This indicator is useful in describing which countries have a formal and complete policy and which are lacking, and thus where policy development work is most needed.

Although this indicator measures the commitment of an NTP to HIV control, a similar indicator is needed to measure the commitment of national HIV/AIDS programs to TB; for example, a national HIV/AIDS control policy, endorsed by government, addresses the link between TB and HIV, as well as the importance of TB as a major treatable and preventable cause of morbidity and mortality among PLWHA. A full description of this indicator is forthcoming from WHO.

# 4. Diagnosis and Laboratories

## Introduction

There are three components relating to diagnosis and laboratories:

- Functional network of quality laboratory services
- Health facility staff with an appropriate clinical suspicion for TB among their patients
- Use of laboratory services by clinicians and accurate diagnosis and classification of TB cases, especially of those cases that are not smear positive.

### *Laboratory Services*

Laboratory services should be the cornerstone of a TB control program. They are clearly identified as one of the elements of the DOTS strategy, yet the public health laboratory network has traditionally been a neglected component in TB control activities, and this network remains one of the weakest links in many NTPs.

Any discussion or assessment of the laboratory's role in TB control should go beyond the technical aspect of performing smears. The following aspects should be considered:

- To what extent is the national laboratory a part of the NTP, and what is its role in decision-making regarding laboratory issues?
- Does the national reference laboratory belong to a supranational reference laboratory for culture examination and drug susceptibility testing?
- Has a needs assessment for laboratory services been conducted, examining human and capital resources?
- Is there a strategic plan for laboratory improvement, including a budget that considers the needs identified?
- Is there a national smear microscopy laboratory manual?
- Are standard operating procedures (including biosafety procedures) distributed and in use by all diagnostic units?
- Have internal and external quality assurance programs been implemented?
- Is there a plan for maintenance of laboratory equipment?

- Has a program for supervision of peripheral and intermediate laboratories been implemented?
- Have all aspects of training in smear microscopy been addressed (both initial training and retraining in the case of substandard performance)?
- Do smear microscopy services adequately "cover" the population?
- Are culture examination and drug susceptibility testing available at the appropriate level?

Internationally accepted indicators have not yet been developed for many aspects of laboratory performance. This is due in part to the difficulty of assessing quality, the overlap in jurisdiction of "laboratory issues" within MOH, and the fact that many aspects of "diagnosis" are beyond the control of the laboratory. For instance, failure to obtain a sufficient number of smears from a TB suspect may relate to the patient's behavior and the ability of the health facility staff to explain the importance of the examination or the timeliness of the logistical system that transports specimens, smears, or smear results between health centers and microscopic centers. Nonetheless, a few standard indicators related to laboratory function are presented in this section.

Within the domain of laboratory services, direct examination of sputum for *M. tuberculosis* remains the key test for diagnosis of pulmonary TB. The Ziehl-Neelsen technique for staining acid-fast bacilli (AFB) has remained the method of choice for TB diagnosis for many decades. The technique is fast, has high specificity in high-prevalence countries, and enables the immediate identification of those patients who are most infectious and usually most ill. Moreover, microscopy is also the cheapest and most simple technique, applicable to the most difficult environments. The technique for examination of AFB by fluorescence microscopy (FM) on the basis of auramine staining can be used as well. FM is widely used in industrialized countries and has been introduced in developing countries in laboratories with workloads of more than 50 slide examinations per day.

Optimal performance in smear microscopy requires good laboratory practices (GLP). GLP involves proper smearing, staining, and reading techniques, and it is contingent on good equipment and reagents and a safe laboratory environment. Smearing, staining, and reading practices can be maintained and improved through training of laboratory technicians, plus regular supervision. For further improvements of the reliability and efficiency of the lab technicians' work, a quality assurance program is required, involving both internal activities (rechecking of slides and proficiency testing) and periodic external reviews.

It is not enough that individual laboratories work well; a comprehensive network is crucial for good TB control. A network links health facilities to microscopic units in such a way that people (or sputum samples or slides, depending on how the network is designed) are moved quickly and conveniently to obtain the diagnosis. In poorly functioning networks, the delay between obtaining a sputum smear and transmitting the smear examination results back to the health facility may lead to the loss of follow-up of suspects who are not aware of their diagnosis.

### *Clinical Suspicion (Case-Finding Effort)*

To diagnose pulmonary TB among symptomatic people presenting themselves to health facilities, clinicians must be mindful of TB as a possible diagnosis, and they must be able to recognize a TB "suspect" (someone with pulmonary symptoms, including prolonged cough). Then they must think to order the appropriate examinations (i.e., sputum smear examination with or without chest radiograph). The volume of TB suspects examined over time and the proportion of suspects who are found to be smear positive provide evidence that health facilities are making an effort in terms of case-finding. Another measure of case-finding effort and appropriate use of sputum smear microscopy to diagnose TB cases is the proportion of diagnostic smears to suspects examined. These two indicators are presented in this section.

### *Diagnostic Performance*

Another aspect of diagnosis is the work-up of smear-negative and extrapulmonary cases. It is relatively easy for health facility staff with a low level of medical training to diagnose smear-positive pulmonary TB cases; however, diagnosis of smear-negative and extrapulmonary TB cases may involve considerable expertise in reading chest radiographs and eliminating alternative diagnoses. One indicator in this section deals with the diagnosis of smear-negative pulmonary TB cases.

### Indicators

- Existence of comprehensive laboratory network
- TB microscopy coverage
- TB microscopy units with adequate workloads
- TB microscopy units submitting slides for rechecking
- TB suspects who are smear positive
- Smear-negative cases properly diagnosed
- Detected smear-positive cases registered for treatment (inverse of primary default rate)

## Resources

Aziz MA et al., eds. *Guidelines for surveillance of drug resistance in tuberculosis*. Geneva, World Health Organization, 2003 (WHO/CDS/TB/2003.320).

Enarson D et al. *Management of tuberculosis: a guide for low income countries*. Paris, International Union Against Tuberculosis and Lung Disease, 2000.

*External quality assessment for AFB smear microscopy*. Washington, DC, Association of Public Health Laboratories, 2002.

Kivihya-Ndugga L et al. A comprehensive comparison of Ziehl-Neelsen and fluorescence microscopy for the diagnosis of tuberculosis in a resource-poor urban setting. *International Journal of Tuberculosis and Lung Disease*, 2003, 7(12):1163–1171.

*Laboratory services in tuberculosis control. Part I: organization and management*. Geneva, World Health Organization, 1998 (WHO/TB/98.258).

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Rieder HL, Enarson DA. A computer-based ordering system for supplies in national tuberculosis programs. *Tubercle and Lung Disease*, 1995, 76:450–454.

Rieder HL et al. *The public health service national tuberculosis reference laboratory and the national laboratory network: minimum requirements, role and operation in a low-income country*. Paris, International Union Against Tuberculosis and Lung Disease, 1998.

Van Deun A et al. Reproducibility of sputum smear examination for acid-fast bacilli: practical problems met during cross-checking. *International Journal of Tuberculosis and Lung Disease*, 1999, 3(9):823–829.

**Indicator 4.1**

# EXISTENCE OF COMPREHENSIVE LABORATORY NETWORK

## Definition

The existence of a comprehensive laboratory network, organized according to three levels: peripheral (often called "district"), intermediate (often called "regional"), and central (often called "national"). This is a yes/no indicator.

## What It Measures

This indicator measures the capacity of the TB control program to accurately diagnose and monitor TB patients at all levels of the public health service delivery system and perform other higher level laboratory functions, such as mycobacterial drug resistance surveillance.

## How to Measure It

This indicator is measured by an assessment of at least one laboratory at each level to determine the existence of the following minimum components of a comprehensive laboratory network:

- Peripheral laboratories are capable of performing sputum smear microscopy.
- Intermediate laboratories are capable of providing supervision, monitoring, training, and quality assurance to peripheral laboratories as well as performing sputum smear microscopy and culture examination.
- Central laboratories are capable of performing sputum smear microscopy, culture examination, and drug susceptibility testing. Also, the central level must be capable of providing training, performing quality assurance and proficiency testing, and conducting drug resistance surveillance among new and previously treated cases.

These three levels must also be connected through the following:

- Referral and communication mechanisms
- An established system of supervision.

## Data Sources

- TB laboratory register and forms

## Frequency & Function

This indicator should be measured annually until established.

## Strengths & Limitations

The existence of a laboratory network is not a guarantee of adequate performance, because low quality may persist at any level.

**Indicator 4.2**

# TB MICROSCOPY COVERAGE

## Definition 1

Percentage of all TB microscopy units that cover a population size within the recommended range of 50,000 to 150,000 inhabitants.

$$\frac{\text{Number of TB microscopy units that cover a population of a size within a recommended range}}{\text{Total number of TB microscopy units}} \times 100$$

## Definition 2

Average population per TB microscopy unit.

$$\frac{\text{Total population}}{\text{Total number of TB microscopy units}} \times 100{,}000$$

## What It Measures

There are two measures of TB microscopy assessing the adequacy of population coverage by TMUs. The population covered by a TMU should neither be too large, since this could result in poor diagnostic quality owing to work overload of laboratory staff, nor too low, since this could result in poor diagnostic quality owing to a lack of routine use of the necessary skills. The recommended population size per microscopy unit is between 50,000 and 150,000. In most settings, this size results in workloads within the recommended rage of 2 to 20 smears per day. The recommended range of population sizes is relatively large because of the variation of geographical settings within a country. For example, a smaller population per unit may be acceptable in rural areas with low population density. On the other hand, in urban areas, with a higher population density, the population per unit may be relatively large. Additionally, the interpretation of this indicator depends greatly on the underlying prevalence of TB.

## How to Measure It

1. The number of inhabitants that each microscopy unit serves is needed. This information should be available at the microscopy unit or MOH. If this number falls within the recommended range (50,000 to 150,000), the microscopy unit is counted in the numerator. The total number of microscopy units for which this information is available is the denominator.

2. The numerator is available from the most recent census data. The denominator is available from the NTP.

## Data Sources

- Census statistics
- NTP records
- MOH records

## Frequency & Function

This indicator should be measured annually for planning purposes.

## Strengths & Limitations

Overlap in coverage area between central and peripheral sites may obscure measurement of this indicator. For example, the population coverage for a microscopy unit at a hospital may be reported as relatively large, but the actual population coverage may be lower if additional units at peripheral levels (e.g., health centers) exist. Therefore, it is necessary to be comprehensive in the determination of the actual number of TMUs for a given population. The second calculation to measure TB microscopy coverage is a crude number. It does not consider urban or rural population differences unless the total population and the number of units can be disaggregated into urban and rural groups.

**Indicator 4.3**

# TB MICROSCOPY UNITS WITH ADEQUATE WORKLOADS

## Definition

Percentage of all TB microscopy units with an average daily staff workload within a recommended range (2 to 20 slides per day per microscopist).

$$\frac{\text{Number of TMUs with an average daily staff workload within a recommended range}}{\text{Total number of TMUs for which data are available}} \times 100$$

## What It Measures

This indicator assesses the appropriateness of workloads for laboratory staff. The number of patients should neither be too large, since this could result in poor diagnostic quality owing to work overload of laboratory staff, nor too low, since this could result in poor diagnostic quality owing to a lack of routine use of the necessary skills. The recommended workload for one laboratory technician to be able to ensure adequate quality is between 2 and 20 slides per day (a day being equal to 8 hours) with a light microscope (minimum of 10 slides per week and maximum of 20 per microscopist per day on average).

The recommended range for an acceptable workload is relatively large because of differences in population densities (Indicator 4.2). In rural areas with a low population density, a minimum number of laboratories may be required to ensure access to diagnostic facilities, even if the average number of slides examined becomes relatively low. It should nevertheless not be fewer than two slides per day on average. The workload per laboratory staff member should not exceed 20 slides per day with a light microscope. More than one microscopist may use one microscope (the limitation is on staff reading of slides). Fluorescent microscopy should be considered when the workload exceeds 50 slides per day.

## How to Measure It

Information on laboratory staff workloads can be obtained from laboratory registers (in units using light microscopes) by counting the number of slides examined per microscopist per day. This information should be used to determine the number of laboratories that have a staff workload within the recommended range. This is the

numerator. The total number of TB microscopy laboratories for which information is available is the denominator.

## Data Source

- TB laboratory register

## Frequency & Function

This indicator should be measured annually for planning purposes at the facility, district, regional, and central levels.

## Strengths & Limitations

The value of this indicator will be low if staff workloads are outside the recommended range, either above or below. The reasons for an unacceptably high workload include an inadequate number of TMUs or laboratory technicians for a given population, or overly suspicious primary health care workers. The reasons for an unacceptably low workload include having too many TB microscopy laboratories or laboratory technicians, or low levels of cases declared suspicious by providers. Additionally, the value must be interpreted in the context of the numerous activities, not all TB related, that a laboratory technician performs on a daily basis.

**Indicator 4.4**

# TB MICROSCOPY UNITS SUBMITTING SLIDES FOR RECHECKING

## Definition

Percentage of all TB microscopy units for which slide rechecking results, one component of a quality assurance (QA) system, are available.

$$\frac{\text{Number of TB microscopy units for which slide rechecking results are available during a specified period}}{\text{Total number of units performing TB smear microscopy during the same period}} \times 100$$

## What It Measures

This indicator measures the existence of one critical component of a QA system, which is defined as a system designed to continuously improve the reliability, efficiency, and use of TB laboratory services. NTPs should have a QA system that covers all TB laboratories in the country. A low proportion of TMUs with QA results indicates the need for further development of the laboratory QA system.

## How to Measure It

The presence of slide rechecking results should be verified at the laboratory. Most laboratories keep records of the slides that were sent for rechecking and the results that were sent back to them from the regional or central levels. The number of laboratories that have slide rechecking results available is the numerator. The total number of TB microscopy units in the respective areas assessed is the denominator.

## Data Sources

- Laboratory records containing QA results

## Frequency & Function

Since QA is a routine function of the laboratory network, this indicator can be measured quarterly or annually during monitoring visits.

## Strengths & Limitations

This indicator is a proxy for measuring the existence of a complete QA system for laboratory control, as described above. Rechecking of slides is a fairly quick and easy measure to demonstrate that some aspect of quality control is being implemented at the laboratories. This indicator does not measure the quality of smear microscopy at the laboratories; it simply measures whether quality checks are being done.

**Indicator 4.5**

# TB SUSPECTS WHO ARE SMEAR POSITIVE

## Definition

Percentage of TB suspects who are found to be smear positive.

$$\frac{\text{Number of TB suspects found to be smear positive during a specified period}}{\text{Number of TB suspects identified clinically during the same period}} \times 100$$

This indicator is also known as the suspect positivity rate.

## What It Measures

This indicator measures case detection effort among health staff. Increased case detection effort should lead to increased case detection (Indicator 1.1). The target for this indicator should be around 10%: A value higher than 10% may indicate that clinicians are not well aware of TB symptoms and only send those patients at advanced stages of TB for sputum examination. When X-rays are used as a filter to select patients who should have a sputum smear examination, positivity rates are expected to be higher than 10%. A value less than 10% may indicate that the clinicians are referring too many "suspects" for sputum smear examination, and laboratory services can be overburdened with unnecessary negative examinations, which could compromise the quality of their work.

## How to Measure It

The numerator and denominator can be obtained from the TB laboratory register or a "cough register" maintained at the treatment facility. This register lists all TB suspects who have been referred for chest X-ray and/or sputum smear examinations. In this case, each facility—and the district as a whole—can calculate the indicator.

In addition, the health facility can monitor the number of suspects identified per patient population (e.g., per outpatient visits), and the district as a whole can monitor the number of suspects identified per population.

## Data Sources

- TB laboratory register or cough registers

## Frequency & Function

The indicator should be calculated on a quarterly and annual basis.

## Strengths & Limitations

Although this is an indicator of effort among health facility staff at the point where the patient presents through passive case-finding, referral patterns in the community will affect the results. For instance, in a community where private practitioners are skilled at recognizing TB (perhaps with the use of X-ray examination), but refer the patient to public health facilities for sputum examination and possible treatment, the proportion suspects with TB will be high. Similarly, the care-seeking behavior in the community may affect the results. For instance, if care is typically deferred for as long as possible, then many patients qualifying as "suspects" may have a history of cough in excess of 3 weeks, raising the likelihood that TB is the cause of the cough.

A low proportion of suspects may have been classified as smear positive because of poor laboratory function (poor sensitivity in preparing and reading slides from those who are truly smear positive). Although this indicator is useful at an operational level, there are some difficulties in looking at aggregated results at a higher level.

**Indicator 4.6**

# SMEAR-NEGATIVE CASES PROPERLY DIAGNOSED

## Definition

Percentage of all adult smear-negative pulmonary TB cases diagnosed with three smears and chest radiograph according to NTP-recommended diagnostic algorithm.

$$\frac{\text{Number of adult smear-negative pulmonary TB cases diagnosed with at least three negative smears and chest radiograph according to NTP-recommended algorithm during a specified time period}}{\text{Total number of adult pulmonary smear-negative cases diagnosed during the same period}} \times 100$$

## What It Measures

The indicator assesses the adequacy of diagnosis for smear-negative cases. If diagnostic algorithms are not strictly followed, too many smear-negative TB cases are treated, which results in an unnecessary burden on the NTP and the general health system. A low value points to the need for intensified training and supervision of staff in order to encourage use of the recommended algorithm for diagnosing smear-negative TB.

## How to Measure It

Measurement of this indicator requires a review of patient treatment cards for adult smear-negative cases registered during the specified time period with a checklist of components for the NTP-recommended algorithm. The numerator is the number of adult smear-negative cases with evidence of three smears and chest radiograph according to the NTP-recommended algorithm for diagnosing smear-negative TB. The denominator is the total number of adult smear-negative cases registered during the period, according to the laboratory register.

## Data Sources

- NTP diagnostic algorithm for smear-negative TB
- TB laboratory register
- TB treatment cards

## Frequency & Function

This indicator should be measured annually at the facility level during monitoring visits.

## Strengths & Limitations

The determination of this indicator is dependent on the accuracy of information obtained by adhering to the NTP-recommended algorithm for diagnosing smear-negative TB. This indicator is complementary to Indicator 2.4. If the percentage of adult smear-positive cases is less than 50%, then this indicator will help to explain whether the smear-negative cases have been correctly diagnosed.

**Indicator 4.7**

# DETECTED SMEAR-POSITIVE CASES REGISTERED FOR TREATMENT (INVERSE OF PRIMARY DEFAULT RATE)

## Definition

Percentage of all detected smear-positive pulmonary TB cases that have initiated treatment.

$$\frac{\text{Number of new smear-positive pulmonary TB cases that have initiated treatment during a specified time period}}{\text{Total number of new smear-positive cases detected during the same period}} \times 100$$

## What It Measures

This indicator measures whether or not patients identified by the laboratory as having smear-positive pulmonary TB actually initiate treatment. This indicator is important because it is a proxy for determining 1) whether information flows from the laboratories to treatment facilities, 2) whether a mechanism exists for tracing and informing patients if they do not return to the facility to receive their results, and 3) whether there are adequate resources (e.g., drugs, trained staff) to start treatment. A high proportion of diagnosed patients who are not started on treatment indicates organizational problems, resulting in a risk of death to the diagnosed patient and further transmission to the general population.

## How to Measure It

The numerator is the total number of new smear-positive pulmonary TB cases in the TB register during a specified period that have initiated treatment. The number of all smear-positive cases diagnosed (from the laboratory register) in the same period is the denominator. Diagnosed cases properly referred for treatment in another district should not be included in the denominator.

## Data Sources

- TB laboratory register
- TB register

## Frequency & Function

The indicator should be reported quarterly and annually for facilities, for basic management units (district), and as a summary statistic for regions and the national level.

## Strengths & Limitations

Patients lacking documentation of treatment initiation may have started treatment in another district or in a private facility, and the facility that originally diagnosed the patient may not have received or recorded information regarding the referral or transfer.

# 5. Case Management and Treatment

## Introduction

Effective case management of TB is critical to achieving high cure rates and overall program success under the DOTS strategy. A cornerstone of case management is also one of the central DOTS elements: administration of short-course chemotherapy under direct observation by health workers or other trained individuals. A key to the success of case management is a patient-oriented environment and a supportive relationship between the patient and the treatment observer. The essential elements of case management and treatment that provide the foundation for this DOTS component include:

- Correct use of treatment protocols by diagnosing clinicians, including prescription of the correct medications at the appropriate dosages for the proper length of time for the initial and continuation phases of treatment (Indicator 5.2)
- Direct observation of therapy by regularly supervised health workers or other trained individuals (Indicator 5.1)
- Prevention of default and treatment interruption and follow-up of lost patients when necessary (Indicator 2.13)
- Recognition and management of adverse reactions to medication
- Monitoring response to treatment with smear examinations at the end of the second month, during the fifth month, and in the final month of 6- and 8-month regimens (Indicators 2.7 and 2.8)
- Determination of the treatment outcome for each patient (Indicators 1.2 and 2.9 through 2.14).

Additionally, some program models include elements of case management, such as provision of food supplements; nutritional counseling; infection control counseling to avoid transmission of TB to family members, friends, and/or coworkers; VCT for HIV; direct financial assistance for transportation to and from clinics for D.O.T.; and home visits to provide D.O.T. or follow-up care for severely ill patients.

Measurement of the provision of D.O.T. is challenging; it may be necessary to consult multiple sources of information to verify that treatment is routinely administered under direct observation. Likewise, facility-level measurement of some indicators can be burdensome. For example, review of individual medical records to check proper

dosage and duration of medication during the initial and continuation phases is time consuming when done correctly.

Several of the indicators for measuring effective case management should be measured at the facility level and are best suited for special surveys. Thus, they can be reported for an individual facility or used as summary indicators at the district or national level, depending on the scope of the survey. On the other hand, smear conversion and treatment outcomes are routinely reported to the NTP on a quarterly and annual basis at every level of the NTP.

## Indicators

- Patients under direct observation of therapy
- New TB patients who were prescribed the correct regimen

## Resources

*An expanded DOTS framework for effective tuberculosis control. WHO report 2002*. Geneva, World Health Organization, 2002 (WHO/CDS/TB/2002.297).

Enarson D et al. *Management of tuberculosis: a guide for low income countries*. Paris, International Union Against Tuberculosis and Lung Disease, 2000.

Pio A, Chaulet P. *Tuberculosis handbook*. Geneva, World Health Organization, 1998 (WHO/TB/98.253).

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*Treatment of tuberculosis: guidelines for national programs*. Geneva, World Health Organization, 2003 (WHO/CDS/TB/2003.313).

World Health Organization, International Union Against Tuberculosis and Lung Disease, Royal Netherlands Tuberculosis Association. Revised international definitions in tuberculosis control. *International Journal of Tuberculosis and Lung Disease*, 2001, 5(3):213–215.

**Indicator 5.1**

# PATIENTS UNDER DIRECT OBSERVATION OF THERAPY

## Definition

Percentage of TB patients whose therapy was directly observed by a trained, regularly supervised individual according to NTP guidelines.*

$$\frac{\text{Number of new smear-positive pulmonary TB patients who report observation of every dose of medication per NTP guidelines}}{\text{Total number of new smear-positive pulmonary TB patients interviewed regarding direct observation of therapy}} \times 100$$

**NTP guidelines should specify D.O.T. for at least the first 2 months of treatment. In some countries, the guidelines may specify direct observation for the full course of treatment if rifampicin is used in the continuation phase.*

## What It Measures

This indicator measures an essential element of the DOTS strategy: direct observation of therapy to ensure patient and provider adherence to treatment. WHO recommends that a health care worker or trained and regularly supervised person observe the patient swallowing each dose of medicine and record the dose on the individual treatment card throughout the initial phase of treatment. Each facility should attempt to achieve 100% on this indicator, to comply with international guidelines and prevent drug resistance.

## How to Measure It

The numerator for this indicator is determined through surveys of patients who are receiving treatment or who recently completed treatment. Ideally, these interviews should take place in private, as the presence of treating clinicians may discourage patients from admitting that any doses have not been directly observed. The patient should be asked to describe how the medication is distributed, and how or when it is taken. If patients are hospitalized during the initial phase, it should not be assumed that D.O.T. is practiced, and the same methods of treatment should be used to determine who has received D.O.T. All health facilities should aim to reach 100%.

## Data Sources

- Surveys of TB patients (e.g., exit interviews with patients or at their household)
- Interviews with TB patients and treatment providers

## Frequency & Function

This indicator should be measured on an annual basis for the purposes of quality monitoring.

## Strengths & Limitations

This indicator reflects the degree to which the directly observed therapy component of DOTS has been implemented by the NTP; thus, it may help explain trends in poor treatment outcomes if the proportion of directly observed patients is low. However, the reasons for not achieving a high proportion of directly observed therapy are numerous, and it may be difficult to determine the specific problem area that results in a low value.

**Indicator 5.2**

# NEW TB PATIENTS WHO WERE PRESCRIBED THE CORRECT REGIMEN

## Definition

Percentage of new TB patients who were prescribed the correct regimen of medications, as described by NTP guidelines.

$$\frac{\text{Number of new TB patients who were prescribed the correct regimen of medications during a specified period}}{\text{Total number of new TB patients who completed treatment during the same period}} \times 100$$

## What It Measures

This indicator measures the correct prescription of anti-TB drugs according to the NTP guidelines. Thus, it is important to measure adherence to protocols for the initial and continuation phases of treatment. To provide adequate treatment, facilities must have the correct drugs available in quantities to support the number of patients currently receiving therapy. Additionally, the prescribing physician must be familiar with treatment protocols, including the correct combination of medications, the proper dosage (according to body weight), proper frequency, and the appropriate duration. All facilities and districts should aim to reach 100% on this indicator.

## How to Measure It

This indicator should be included as part of a facility survey, as correct measurement requires an in-depth review of individual medical records. At the district level, at least 20 treatment facilities should be selected randomly for measurement, and 30 individual medical records from each facility should be reviewed. The following data should be abstracted from each record: patient age and weight as well as the strength, dosage, and frequency of use for each medication prescribed to the patient. Additionally, the start and stop dates for each medication should be recorded. The numerator should include only those patients for whom the correct strength, dosage, and frequency of each medication were prescribed in accordance with NTP recommendations for the initial phase of treatment. The denominator should be the number of records reviewed of patients who completed treatment during the reporting period. This indicator may be calculated separately for initial and continuation phases of treatment.

## Data Sources

- NTP treatment guidelines
- TB register
- Individual medical records, including treatment cards and prescriptions
- Facility survey

## Frequency & Function

This indicator should be measured every 2 to 3 years as part of an in-depth facility survey. It can be modified to evaluate treatment procedures by private practitioners.

## Strengths & Limitations

This indicator yields useful data for not only assessing the proportion of patients on the correct regimen, but also identifying any problems that may result in an incorrect regimen. For example, since data are collected for each medication, the information can be broken down by medication to see whether a shortage of a specific drug is the problem or whether the problem is due to provider mistakes in determining the correct dosage and frequency. However, data collection is time and labor intensive, which means that this indicator is not suitable for routine monitoring.

# 6. Drug Management

## Introduction

One of the five components of the DOTS scheme is an uninterrupted supply of quality-assured drugs. The NTP must ensure that patients have their medicines when they need them to prevent transmission of the disease. Therefore, NTP managers must be involved at all levels of the medicines supply system, including selection, procurement, distribution, use, and quality assurance.

### *Selection*

There are no indicators included in this manual for the selection component of drug management. Even so, the NTP must be a member of the essential medicines committee that updates and approves the standard TB treatment regimens. The committee must select appropriate drugs on the basis of incidence of the disease as well as drug strengths, use of fixed dose combination products, dosage forms, and type of packaging.

### *Procurement*

The NTP should be a major player in estimating final drug quantities needed for the national program, regardless of whether calculations are done centrally or peripherally. In addition, the NTP should communicate to the procurement department other product-related issues, such as providing feedback on problems encountered in treatment centers with the quality of a particular supplier's products and confirming that the procurement department received product quality specifications with the tender documents. A key indicator in this manual concerns the existence of buffer stock (Indicator 6.3). Once buffer stocks are received, they can be shared with district stores as explained within the indicator. When buffer or reserve stocks are procured in addition to the estimated quantities needed, the national program will have sufficient stocks to respond to unplanned occurrences (e.g., an unexpected increase in TB cases).

### *Distribution*

To participate in the supply of quality-assured drugs, the NTP should know that deliveries throughout the national program are made in a timely manner and that good stock management practices are followed within storage facilities. Several indicators in this section allow the NTP to monitor those aspects of drug management. For example, Indicators 6.4 through 6.6 will show whether annual quantity estimates are appropriate and whether the medicines supply system is capable of managing inventories, placing orders, and making deliveries in a timely manner.

### *Use*

The use component of drug management requires that the NTP monitor prescriptions to ensure that medicines are ordered according to the standard treatment guidelines of the country and that directly observed treatment is being used in administering medicines to patients, especially during the initial phase. Indicators for the use component are included in Section 5, Case Management and Treatment.

### *Quality assurance*

Quality assurance applies to all of the drug management components. To ensure that quality products are being used, the NTP must be involved at all levels of the medicines supply system. If there is a requirement that anti-TB drugs used by MOH must first be registered by the drug registration authority, the NTP could be the catalyst to ensure that this is arranged and thus avoid later delays when shipments arrive in-county. In a comprehensive QA system, anti-TB medicine samples of incoming products and of products already in storage and treatment facilities should be pulled and tested. To stay abreast of product quality problems, the NTP should receive reports from the quality control laboratory when anti-TB medicines are found to have problems. The two key indicators included in this section are Indicators 6.1 and 6.2, which measure the existence of a drug quality assurance system and the proportion of anti-TB drugs that meet international minimum quality standards, respectively. A complementary indicator (Indicator 6.8) is also included, which measures the percentage of anti-TB drug samples that fail quality control tests.

It is recognized that NTP managers usually do not have full responsibility for procuring and distributing anti-TB medicines. However, the indicators in this section will allow NTP managers to monitor weaknesses in the procurement and supply of anti-TB medicines as they occur and work with other departments to take appropriate actions, such as training staff, obtaining technical assistance from TB partners, and instituting double checks to validate critical activities. Using these indicators, NTP managers can contribute to an uninterrupted supply of quality-assured drugs for patients in their health systems.

### Indicators

- Existence of a quality assurance system for drug management
- Anti-TB drugs meeting international minimum quality standards
- Existence of buffer stock at central, regional, or district-level facility
- Accuracy of stock records for anti-TB drugs
- Time anti-TB drugs are out of stock—storage facilities
- Time anti-TB drugs are out of stock—treatment facilities

- Basic management units where anti-TB drugs are available
- Anti-TB drug samples that fail quality control tests

## Resources

Brudon P, Rainhorn JD, Reich M. *Indicators for monitoring national drug policies*. Geneva, World Health Organization, 1999 (WHO/EDM/PAR/1999.33).

*Operational guide for national tuberculosis programs on the introduction and use of fixed-dose combination drugs*. Geneva, World Health Organization, 2002 (WHO/CDS/TB/2002.308).

Quick J et al. *Managing drug supply*. Boston, MA, Management Sciences for Health, 1997.

Rational Pharmaceutical Management Plus Program. *Drug management for tuberculosis manual (DMTB)*. Arlington, VA, Management Sciences for Health, 2003.

Trebucq A, Rambert C. *A guide for the procurement of anti-tuberculosis drugs*. Paris, International Union Against Tuberculosis and Lung Disease, 2001.

**Indicator 6.1**

# EXISTENCE OF A QUALITY ASSURANCE SYSTEM FOR DRUG MANAGEMENT

## Definition

Existence of a quality assurance system for drug management that monitors the safety of drugs for use by inhabitants of the country. This is a yes/no indicator.

## What It Measures

This indicator measures whether a comprehensive QA system exists and includes agencies or committees for registering drugs, selecting quality products and suppliers, conducting product certification, developing contract specifications, and performing physical inspections and laboratory analyses when drugs are received, as well as feedback procedures for reporting drug problems. The availability of high-quality drugs is critical to the successful management of TB in countries with multiple sources for anti-TB drugs (e.g., imported from several different countries and/or produced locally).

## How to Measure It

The indicator is measured by reviewing MOH documents describing the QA system, because these documents are rarely available from the NTP. The QA system can consist of one agency or many, but it must conduct all of the activities mentioned above. A health system could use the subindicators to identify specific weaknesses in the quality system. The overall indicator should be scored as a "yes" only if all of the following components are present:

- Existence of drug legislation and regulation
- Existence of registration service
- Availability of inspection service
- Availability of laboratory testing service.

## Data Sources

- MOH documents
- National Pharmaceutical Committee documents

## Frequency & Function

This indicator should be reported annually for national use.

## Strengths & Limitations

This indicator is not limited to TB, rather the existence of QA standards is critical for all medications and for the health system in general. In many countries, a drug QA system is already in place. This indicator is an additional check on the quality of anti-TB drugs manufactured locally and/or procured internationally by the health system. The indicator may not be appropriate for external monitoring, especially on a regular basis. Some MOH documents may describe a complete QA system, but in reality, it is only partially functional. This indicator measures the presence of the system, but it does not assess its function.

**Indicator 6.2**

# ANTI-TB DRUGS MEETING INTERNATIONAL MINIMUM QUALITY STANDARDS

## Definition

Percentage of anti-TB drugs that meet the batch certificate component of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

$$\frac{\text{Number of batches of anti-TB drugs procured locally and internationally where a batch certificate was received and showed acceptable results during a specified time period}}{\text{Total number of batches of anti-TB drugs procured during the same time period}} \times 100$$

## What It Measures

Availability of high-quality drugs is critical to the successful management of TB, particularly to avoid the emergence of drug-resistant strains. This indicator measures whether a minimum standard has been met in the procurement of anti-TB drugs both from local and international suppliers. It can also be used for other drugs procured by a health system. The QA model "Scheme on the Quality of Pharmaceutical Products Moving in International Commerce" requires that health systems obtain three certificates when procuring drugs: 1) product certificate, a description of the product and its specifications; 2) statement of licensing of a pharmaceutical product, a business license to produce the product; and 3) batch certificate of a pharmaceutical product, the results of quality analysis and inspection for each batch of product manufactured.

To meet the minimum standard, this indicator requires that the batch certificate is requested and received and that the data are acceptable. The batch certificate is chosen as the minimum because all manufacturers that follow good manufacturing practices (GMP) should produce this report and thus be able to supply it to the procuring agency. Also, the batch certificate can be easily examined by an evaluator to calculate this indicator. (Appendix E contains a model batch certificate.) Information on bioavailability of rifampicin in fixed dose combination products is a key component of QA; even though this information is not included on a batch certificate by the manufacturer, the NTP should communicate with the drug registration authority (DRA) to ensure that the rifampicin bioavailability data have been received and are acceptable.

## How to Measure It

The indicator is measured by reviewing drug records from the procurement agent of the NTP and the DRA, if one exists. The numerator is the number of TB drug batches received by the program during the specified time period. Batch certificates should be requested from the procurement agent or the DRA for each batch received. The number of batches with a batch certificate showing acceptable results is recorded as the denominator.

## Data Sources

- Procurement agency records
- DRA records

## Frequency & Function

This indicator should be reported annually for national use

## Strengths & Limitations

The WHO QA scheme was designed for internationally purchased drugs, but WHO and its partners want to promote quality drugs manufactured by local companies as well. The minimum acceptable standard would be to receive a batch certificate indicating the acceptability of each batch of a drug received since all manufacturers who follow GMP standards should produce this document as a matter of course. This indicator allows quick identification of potential serious QA problems within the health system (i.e., if the NTP is unable to produce the required supporting documentation).

**Indicator 6.3**

# EXISTENCE OF BUFFER STOCK AT CENTRAL, REGIONAL, OR DISTRICT-LEVEL FACILITY

## Definition

The existence of a buffer stock of anti-TB drugs to ensure regular supplies at TB treatment centers. The standard recommendation is to have a 6-month buffer stock at central storage areas and a 3-month buffer stock at regional or district levels. This is a yes/no indicator.

## What It Measures

This indicator measures whether the NTP has the resources and organizational capacity to avoid drug stockouts by keeping additional quantities of drugs on hand. Buffer stock is an essential element of the drug supply system for avoiding stockouts at treatment centers. It is difficult for NTPs to determine exact quantities of anti-TB drugs needed from one procurement period to another because of inaccuracy in the reporting system, insufficient financial resources, and supplier delays.

## How to Measure It

This indicator is determined after a review of quantification records of the NTP or essential drugs program. From the records, data collectors will observe whether a buffer stock has been calculated, ordered, and received at the central and district levels. For example, if the NTP procures once annually, then in addition to the quantity needed for the 12 months, an additional 6-month buffer stock should be procured at the same time. At the district level, the quantity needed for the next 3 months is ordered from the central warehouse plus an additional buffer stock equal to 3 months' treatment. An inadequate buffer stock of any individual anti-TB drugs would result in a "no" score for this indicator regardless of whether or not all other drugs had adequate buffer stock.

## Data Sources

- TB drug quantification records
- Procurement records

## Frequency & Function

This indicator should be reported annually for national warehouses and biannually for regional and district warehouses.

## Strengths & Limitations

This indicator does not measure whether problems exist further down the supply line, whereby stockouts could still occur at the treatment center level. However, this indicator will measure whether the NTP has the ability and resources to avoid stockouts at storage levels to regularly supply anti-TB medications.

**Indicator 6.4**

# ACCURACY OF STOCK RECORDS FOR ANTI-TB DRUGS

## Definition

Percentage of stock records that correspond with physical counts for a set of anti-TB tracer drugs in drug storage facilities.

$$\frac{\text{Number of stock records that correspond with physical counts}}{\text{Total number of stock records examined}} \times 100$$

## What It Measures

Managing drug storage facilities appropriately is important for providing a constant supply of anti-TB drugs to treatment centers. One important activity is the accurate accounting of drugs that are received and distributed by the storage facility. When physical counts of drugs are different from those on stock records, under- or overordering is likely to result.

## How to Measure It

The quantity of each anti-TB drug in stock must be counted in the warehouses and storage areas of health centers. This quantity is compared with the quantity of each drug documented on the individual stock cards. If this quantity is more than or less than the physical quantity counted, this drug is recorded as not corresponding with stock records. The number of stock records corresponding with physical counts should be summed and then divided by the total number of stock records examined. This number is multiplied by 100 for obtaining the percentage of stock records that are accurate in the storage facility.

## Data Sources

- Storage facility stock cards for individual drugs
- Physical observations at the facility

## Frequency & Function

This indicator should be reported biannually for national, regional, and district stores

## Strengths & Limitations

This indicator allows managers to monitor the work of stock managers and identify weaknesses in maintaining a constant supply of anti-TB drugs. The frequency of reporting this indicator may be changed to annually once compliance by stock managers has been stabilized.

**Indicator 6.5**

# TIME ANTI-TB DRUGS ARE OUT OF STOCK—STORAGE FACILITIES

## Definition

Average percentage of time that first-line anti-TB drugs are not available in storage facilities.

$$\frac{\text{Total number of stockout days for all first-line drugs stocked}}{(365 \times \text{number of anti-TB drugs})} \times 100$$

## What It Measures

This indicator measures a key DOTS component, uninterrupted drug supply. This is based on the principle that all core anti-TB drugs used in the program must be available when the patient needs them for appropriate treatment and for preventing development of MDR-TB. This indicator should be used in conjunction with Indicator 6.7 for understanding the actual availability of anti-TB drugs and underlying management practices.

## How to Measure It

Data should be collected from as many storage facilities at the central and district levels as possible. This indicator is calculated by recording the number of days that any drug was out of stock in the past year (or the past 12 months) as recorded on the stock cards and by summing the total number of days out of stock. The number of days is then divided by 365 times the total number of drugs normally stocked, and this fraction is multiplied by 100.

## Data Sources

- Storage facility stock cards of individual drugs

## Frequency & Function

This indicator should be reported quarterly for national, regional, and district stores.

## Strengths & Limitations

Measurement of this indicator should be a routine activity for internal monitoring. When used during an external monitoring review, an in-depth analysis may not be possible since data are collected only from those sites visited by the evaluation team. Recall bias on the part of providers may result in an inaccurate numerator, and it may be necessary to extrapolate from the most recent quarter to assess stockouts in the previous year. Some health systems do not consistently record movements of stock into and out of the treatment areas.

**Indicator 6.6**

# TIME ANTI-TB DRUGS ARE OUT OF STOCK—TREATMENT FACILITIES

## Definition

Average percentage of time that first-line anti-TB drugs are not available in treatment facilities.

$$\frac{\text{Total number of stockout days for all first-line drugs stocked}}{365 \times \text{number of anti-TB drugs in treatment facilities}} \times 100$$

## What It Measures

The availability of medication is critical to the successful management of TB, and an uninterrupted supply of drugs at treatment centers is crucial to cure patients and to avoid the emergence of drug-resistant strains of TB. This indicator measures a key DOTS strategy component, uninterrupted drug supply. This is based on the principle that all core anti-TB drugs must be available when the patient needs them for appropriate treatment and for preventing development of MDR-TB. This indicator should be used in conjunction with Indicator 6.7 for understanding the actual availability of anti-TB drugs and underlying management practices.

## How to Measure It

Data should be collected from as many treatment facilities at central, regional, and district levels as possible. This indicator is calculated by recording the number of days that each drug was out of stock in the past year (or the past 12 months) as recorded on the stock cards and by summing the total number of days out of stock for any drugs. The number of days is then divided by 365 times the total number of drugs normally stocked, and this fraction is multiplied by 100.

## Data Sources

- Facility stock cards of individual drugs

## Frequency & Function

This indicator should be reported quarterly for regional, district, and community health centers.

## Strengths & Limitations

This indicator should be a routine activity for internal monitoring. However, when used during an external monitoring review, an in-depth analysis may not be possible since data are collected only from those sites visited by the evaluation team.

**Indicator 6.7**

# BASIC MANAGEMENT UNITS WHERE ANTI-TB DRUGS ARE AVAILABLE

## Definition

Proportion of basic management units where anti-TB drugs are present on the day of the survey.

$$\frac{\text{Number of basic management units visited where anti-TB drugs are present}}{\text{Total number of basic management units visited}} \times 100$$

## What It Measures

The availability of medication is critical to the successful management of TB. This indicator measures the performance of the country's procurement and inventory management system to provide drugs at treatment units when patients need them. This indicator should be used in conjunction with Indicators 6.5 and 6.6 for understanding the actual availability of anti-TB drugs and underlying management practices.

## How to Measure It

Data should be collected from as many TB BMUs as possible. This indicator is calculated by recording which anti-TB drugs are available on the shelves and in storage areas on the day of the visit for each management unit. This is compared with a list of drugs that should be available. Expired drugs should not be included as being available since they cannot be used to treat patients. The units that have any missing anti-TB drugs should be documented. The number of BMUs where all anti-TB drugs are available on the day of the survey is summed. This number is then divided by the total number of BMUs visited.

## Data Sources

- Drugs stocked in TB BMUs and stock records

## Frequency & Function

This indicator should be reported quarterly for national use.

## Strengths & Limitations

This indicator could be a routine activity for internal monitoring. However, when used during an external monitoring review, an in-depth analysis may not be possible since data are collected only from those sites visited by the evaluation team.

**Indicator 6.8**

# ANTI-TB DRUG SAMPLES THAT FAIL QUALITY CONTROL TESTS

## Definition

Percentage of anti-TB drug samples that failed quality tests in the country's quality control analysis laboratory.

$$\frac{\text{Number of anti-TB drug samples that failed quality control testing}}{\text{Total number of anti-TB drug samples tested in the country's quality control analysis laboratory}} \times 100$$

## What It Measures

Anti-TB drugs must be purchased from reputable sources and certified by the authority in the recipient country to be safe, efficacious, and of good quality. The drug supply system must take care to store drugs appropriately. This indicator measures the proportion of anti-TB drugs tested that did not meet the standard quality criteria set by the recipient country. Ideally, no samples should fail quality testing, but this is usually not the case. Failed samples indicate poor manufacturing and delivery practices on the part of the supplier and poor distribution practices on the part of the recipient country.

## How to Measure It

The total number of anti-TB drug samples that failed quality control testing is recorded and divided by the total number of anti-TB drug samples actually tested. This number is multiplied by 100 for obtaining the percentage of drugs that failed quality control tests.

## Data Sources

- Quality control laboratory register
- MOH reports

## Frequency & Function

This indicator should be reported annually for national use.

## Strengths & Limitations

This indicator will not be useful in the few countries that do not have a local product quality testing laboratory. Such countries usually rely on the product manufacturer's quality testing (Indicator 6.2).

# 7. Recording and Reporting

## Introduction

A recording and reporting system that allows assessment of each patient and of overall program performance is an essential element of the DOTS strategy. One key element is the TB patient register, in which the essential data for each patient are recorded in a single line. This allows easy monitoring and supervision, and it consolidates the information on TB patient management for a defined geographical area.

The TB register and the district reports on case detection, sputum smear conversion, and treatment outcomes based on the register provide the basic data to monitor and evaluate the TB program. Completeness and accuracy of data are important for operational and for epidemiological purposes. Such a system is useful not only to monitor progress and treatment outcomes of individual patients, but also to evaluate overall program performance at all levels (national, regional, and district), monitor program activities, and evaluate accomplishments.

Completeness and accuracy of data are key factors in the success of a reporting and recording system. The success of the NTP in controlling TB largely depends on its ability to maintain high cure and treatment completion rates. The NTP must receive complete and accurate information on treatment outcomes for every facility providing TB treatment to measure progress towards achieving high rates of treatment success and to identify weaknesses in the program. Quarterly reports that have missing or inaccurate data directly impact individual patient treatment and program planning.

## Indicators

- Completeness of reporting to NTP
- Accuracy of reporting to NTP

## Resources

*An expanded DOTS framework for effective tuberculosis control. WHO report 2002*. Geneva, World Health Organization, 2002 (WHO/CDS/TB/2002.297).

Pio A, Chaulet P. *Tuberculosis handbook.* Geneva, World Health Organization, 1998 (WHO/TB/98.253).

**Indicator 7.1**

# COMPLETENESS OF REPORTING TO NTP

## Definition

Percentage of basic management units submitting case-finding and treatment outcome reports to the NTP each quarter.

$$\frac{\text{Number of basic management units that submitted case-finding and treatment outcome reports to the NTP in the previous quarter}}{\text{Total number of basic management units required to submit case-finding and treatment outcome reports to the NTP each quarter}} \times 100$$

## What It Measures

This indicator measures the completeness (i.e., submitting both case-finding and treatment outcome reports) and timeliness (i.e., as required by the NTP) of TB report submission, which is essential for efficient program management since it provides the data to evaluate TB program targets, guide efforts to allocate staff, and monitor results. The national TB surveillance system is the primary source of routine TB information. Interpretation of this indicator is based on the total number of reports submitted each quarter. Ideally, all required case-finding and treatment outcome reports should be complete and submitted on time. Each NTP should determine the acceptable level of completeness required for each report in the designated timeframe. If the total number of reports submitted falls below this threshold, this indicates a need to consider an appropriate course of action to increase to the acceptable level the number of complete reports submitted.

## How to Measure It

The numerator is the number of units that submitted case-finding and treatment outcome reports to the NTP in the previous quarter. A unit is included in the numerator only if it submitted both reports to the NTP. The denominator is the total number of units required to submit case-finding and treatment outcome reports to the NTP in the previous quarter. This indicator shows completeness, and it is measured at the central level in a country on a quarterly basis. In addition, the indicator should be separated into different levels of reporting (district to region, region to NTP) and measured for the most recent reporting period for monitoring purposes. Normally, the reports would be found at the district headquarters or, in very large districts, at the subdistrict level.

## Data Sources

- NTP statistics and reports

## Frequency & Function

This indicator should be measured routinely on a quarterly and annual basis unless the NTP guidelines for recording and reporting specify another timeframe.

## Strengths & Limitations

Because recording and reporting systems vary widely in methodology, scope, and objectives, it is important to measure whether the systems function well. The success of any system to record and report depends on the proper balance of logistic support and infrastructure, and the ability of staff. Therefore, although this indicator does not measure the quality of these reports, it does measure whether the existing reporting and recording system is functioning.

**Indicator 7.2**

# ACCURACY OF REPORTING TO NTP

## Definition

Percentage of accurate TB case-finding and treatment outcome reports.

$$\frac{\text{Number of TB case-finding and treatment outcome reports that were recorded completely and accurately}}{\text{Total number of TB case-finding and treatment outcome reports examined}} \times 100$$

## What It Measures

The success of the NTP in controlling TB largely depends on its ability to maintain high cure and treatment completion rates. The NTP must receive accurate information on treatment outcomes for every facility providing TB treatment to measure progress towards achieving high rates of treatment success and to identify weaknesses in the program. Quarterly reports that have missing or inaccurate data directly impact individual patient treatment and program planning.

This indicator measures the completeness and accuracy of the recorded TB case-finding and treatment outcome reports. Any basic management unit of the NTP must use NTP-approved forms to standardize information on case detection and treatment outcomes. Ideally, all required TB case-finding and treatment outcome reports should be complete and accurate. Each NTP should determine the acceptable level of accuracy required for each report in the designated timeframe. If the total number of reports submitted falls below this threshold, this indicates a need to consider an appropriate course of action to increase to the acceptable level the number of complete and accurate reports submitted.

## How to Measure It

An evaluator compares the submitted TB case-finding and treatment outcomes reports with the data recorded in the TB registers, and measures the percentage of accurate and complete TB case-finding and treatment outcome reports. The numerator is the number of correct TB case-finding and treatment outcome reports examined. The denominator will be the total number of TB case-finding and treatment outcome reports examined. It is necessary to gather data on the case-finding report and treatment outcome report separately so that the accuracy and completeness of each can be assessed.

## Data Sources

- NTP statistics and reports
- TB register

## Frequency & Function

This indicator should be measured on a quarterly basis, unless the NTP guidelines for recording and reporting specify another timeframe.

## Strengths & Limitations

This indicator can be used as an internal monitoring mechanism, or it can be used by external consultants for comparing success reported with their assessment of the data. Measurement of this indicator can be labor and time intensive.

# 8. Supervision

## Introduction

Supervision is an integral part of support to all key elements of the DOTS strategy. It is an extension of training as well as a systematic process for increasing the efficiency of health workers by developing their knowledge, perfecting their skills, improving their attitudes towards their work, and increasing their motivation.

A strong TB control program and successful case detection and treatment depend on—

- The creation of a supervisory system from the central to regional level, and from the regional level to BMUs
- Specification of frequency and content of supervisory visits and use of supervisory checklists
- Modifying TB control activities according to feedback from supervisory activities.

Supervision should be performed at all levels of the health infrastructure. All health workers need help to solve problems and overcome difficulties. They also need feedback on their performance and encouragement in their work. Two main levels of supervision are distinguished in this document: 1) supervision of the regions by the central TB unit and 2) supervision of the BMUs by the region.

For supervision to be more efficient from regional level to the BMUs, it is necessary to have guidelines. During a supervision visit, health personnel and patients should be interviewed, information should be collected from different places and from different registers and cards, and supplies must be evaluated. All of these items should be described in these guidelines. Checklists of items that should be assessed during the supervisory visit are useful tools and should be part of the supervision guidelines.

Supervision from the central to intermediate level does not necessitate guidelines but requires a very good knowledge and comprehension of the TB manual of the NTP. Items to check during these central supervision visits should be discussed and identified for each visit well in advance and specifically for each intermediate level.

It is difficult to evaluate supervision. Supervision quality is an important factor for success, but improvement of program delivery does not depend solely on supervision. The elements that are easier to measure are the frequency of supervision and the existence of supervision guidelines. However, the main indication of the efficacy of supervision is the detection and solution of problems and a gradual improvement in the

indicators of program delivery, measured through case detection, smear conversion, and treatment outcome.

## Indicators

- Supervision of DOTS implementation
- Existence of supervision guidelines

## Resource

Pio A, Chaulet P. *Tuberculosis handbook*. Geneva, World Health Organization, 1998 (WHO/TB/98.253).

**Indicator 8.1**

# SUPERVISION OF DOTS IMPLEMENTATION

## Definition

Percentage of planned supervisory visits completed by the TB control program (either from the central to regional level or the regional level to basic management unit) according to the annual work plan.

$$\frac{\text{Number of supervisory visits performed during a specified time period}}{\text{Number of supervisory visits planned according to the annual work plan during the same period}} \times 100$$

## What It Measures

Supervisory visits are a key activity of the NTP. Without supervision, it is difficult to know whether or not DOTS is implemented as planned by the NTP, and how to correct deficiencies. Unscheduled activities, as well as time and logistic constraints, often limit the number of visits originally planned. Inclusion of supervision in the core indicators for the NTPs will reinforce the importance of this activity. This indicator helps the NTP track the frequency of supervisory visits and identifies gaps.

## How to Measure It

A calendar with the planned supervisory visits should be available in the annual work plan; this will provide the denominator. Reports of the supervisory visits performed by the NTP staff should be available; this information is used to determine the denominator. This indicator can be calculated for all supervisory visits or calculated separately for 1) supervision visits from the central to regional levels and 2) supervision visits from the regional to BMUs (e.g., district levels).

## Data Sources

- Annual work plan at the central level
- Reports of the supervisory visits from the central level

## Frequency & Function

This indicator should be reported systematically in the annual report of the NTP.

## Strengths & Limitations

This indicator will measure quantity, but it does not reflect quality. Reading the supervisory reports, monitoring any changes after the supervisory visits, and measuring indicators at the regional levels allow the quality to be evaluated, but it cannot be quantified. Attention should be given to ensure that supervision coverage is addressed in the annual work plan and that this indicator reflects not only that the number of supervisory visits took place according to the work plan, but also that the visits took place in the regions that were specified in the work plan.

**Indicator 8.2**

# EXISTENCE OF SUPERVISION GUIDELINES

## Definition

Guidelines exist for supervision procedures, including checklists that summarize items that should be checked during supervisory visits. This is a yes/no indicator.

## What It Measures

Supervision of the BMU is not an easy task, and a supervisor can be ineffective when attempting to address multiple disease or program concerns during the same visit. Guidelines will help the supervisors to focus on TB control issues in priority order and to evaluate sites in a uniform manner.

## How to Measure It

The indicator is measured by the availability of the supervision guidelines at the appropriate level. The indicator would be scored as a "yes" if it includes all of the basic components listed below.

The following basic components (not an exhaustive list) should be included in the supervision guidelines:

- Review of the TB register
- Review of treatment cards
- Review of laboratory register
- Control of supplies (drugs and laboratory)
- Interviews of some patients.

## Data Sources

- NTP supervision documents

## Frequency & Function

This indicator should be measured annually for planning purposes.

## Strengths & Limitations

Standardized guidelines alone will not ensure effective supervision. The existence of a checklist provides some assurance that the process is standardized.

# 9. Human Resources Development

## Introduction

Developing and maintaining a competent health work force is crucial if the global goals for TB control are to be reached and sustained. Human resources development has, for many years, been limited to either training courses or to development of management systems for handling staff. However, for the overall development of health services and the attainment of specific disease control targets, it is necessary to address the issue of human resource capacity in a much more fundamental way than has been done to date.

NTPs need to ensure that staff at different levels of the health system, clinical and managerial, have the necessary skills knowledge and attitudes (i.e., they are competent) to successfully implement and sustain TB control activities. This includes the implementation of new and revised strategies and tools and, in relation to HIV management, the availability of enough staff to implement the strategy. The NTPs are directly responsible for the competence development of existing staff through training and supervision. The first two indicators presented below relate to the competence of existing staff.

The measurement of the availability of enough staff time to ensure adequate case detection and management is complex. However, even an approximation of staff availability will significantly assist in the program management. The responsibility for designing the human resource (HR) component of health systems typically lies with an HR planning unit (or equivalent department or other entity) of each country's MOH. The HR planning unit helps to establish MOH's overall long- and short-term vision for HR needs, partly on the basis of information supplied by the various technical programs operating within each country. On the basis of information supplied by the HR planning unit, MOH is responsible for ensuring that the health work force is sufficient to meet program needs. However, NTPs should be able to express their specific needs. The third indicator presented below aims at assessing the staffing situation.

From a management point of view for HR development, countries will go through three different phases:

- Initial implementation of the DOTS strategy
- Expansion from pilot areas to the whole country
- Sustainability and quality assurance.

The indicator for HR development presented in this section should be interpreted within the above framework for DOTS expansion.

## Indicators

- TB microscopy units with at least one laboratory technician trained in AFB microscopy
- Health care units with at least one health care professional trained in TB case detection and treatment
- Adequate staffing at all levels to enable implementation of DOTS

## Resources

Pio A, Chaulet P. *Tuberculosis handbook*. Geneva, World Health Organization, 1998 (WHO/TB/98.253).

*Training for better TB control: human resource development for TB control—a strategic approach within country support*. Geneva, World Health Organization (WHO/CDS/TB/2002.301).

**Indicator 9.1**

# TB MICROSCOPY UNITS WITH AT LEAST ONE LABORATORY TECHNICIAN TRAINED IN AFB MICROSCOPY

## Definition

Percentage of TB microscopy units (levels 1, 2, and 3) involved in TB control with at least one member of the staff trained in acid-fast bacilli microscopy for DOTS within the past 3 years. Training includes continuing education and refresher courses.

$$\frac{\text{Number of TB microscopy units with at least one laboratory technician trained in AFB microscopy in the past 3 years*}}{\text{Number of TB microscopy units}} \times 100$$

The denominator can also be "All TMUs involved in DOTS implementation," which could be useful for countries with limited DOTS coverage.

**This number should include new technicians who received their initial training in AFB microscopy within the past 3 years and technicians who received refresher training during the same period.*

## What It Measures

One of the five components of DOTS is the use of smear microscopy to diagnose pulmonary TB. Trained individuals, along with adequate laboratory capacity and supplies, are critical to the delivery of high-quality TB control services. This indicator measures the degree of up-to-date (within the previous 3 years) training of laboratory staff (levels 1, 2, and 3) involved in the implementation of the DOTS strategy. It gives an impression of the system of ongoing training activities and the ability to identify staff turnover in laboratories and ensure the training of new staff, as well as the collaboration between laboratory services and the NTP. It also gives an indication of a country's commitment to HR development for TB control and motivation in following current recommendations and international standards. The NTP should work towards achieving 100% on this indicator or at least an increasing trend over time.

A low numerator would indicate 1) a high staff turnover with no system in place to monitor the presence of trained staff and to take action on identified gaps, and/or 2) a poorly managed training system with few persons trained, and/or 3) an absolute shortage of staff.

## How to Measure It

The number of TMUs with at least one laboratory technician trained in the previous 3 years is the numerator. The total number of TMUs involved in TB diagnosis is the denominator. If no information is available at the administrative level, the number of TMUs having at least one trained professional staff member during the monitoring visit is the numerator, and the total number of laboratories is the denominator.

## Data Sources

- NTP training records
- List of certified laboratory technicians and laboratory of employment
- Interviews with staff members, laboratory technicians

## Frequency & Function

This indicator should be measured annually.

## Strengths & Limitations

Attendance at training courses is a relative measure, and training courses vary greatly in quality (and in duration, content, methodologies used, and skills evaluation). Attendance does not necessarily produce a technician able to perform the key tasks listed in the respective job descriptions related to TB control. Furthermore, ability to perform does not automatically mean a change in laboratory practice to conform to the DOTS strategy. This emphasizes the need for detailed task analysis and specific (formal or informal) job descriptions. In addition, staff might have been trained but are not working in TB control (selection criteria of staff for training).

**Indicator 9.2**

# HEALTH CARE UNITS WITH AT LEAST ONE HEALTH CARE PROFESSIONAL TRAINED IN TB CASE DETECTION AND TREATMENT

## Definition

Percentage of TB treatment facilities with at least one health care professional trained in TB case detection and treatment based on the DOTS strategy (within the past 3 years).

$$\frac{\text{Number of TB treatment facilities with at least one health care professional trained in TB case detection and treatment (within the past 3 years)}}{\text{Total number of TB treatment facilities}} \times 100$$

The denominator can also be "All TB treatment facilities involved in DOTS implementation," which can be useful for countries with limited DOTS coverage.

## What It Measures

Competent staff members are the key to the delivery of high-quality TB control services and the attainment of TB control targets. Measuring the availability of trained staff will provide an immediate indication of the potential for TB case detection and care. The indicator measures the degree of up-to-date (within the previous 3 years) training of professional personnel at facilities involved in the implementation of the DOTS strategy and thus the ability of the health system to deliver high-quality TB control services. It gives an impression of the system of ongoing training activities and the ability to identify staff turnover and ensure the training of new staff. It also gives an indication of the country's commitment to HR development for TB control and motivation in following current recommendations and international standards. The NTP should work towards achieving 100% on this indicator or at least an increasing trend over time.

A low numerator would indicate 1) a high staff turnover with no system in place to monitor the presence of trained staff and to take action on identified gaps, and/or 2) poorly managed training system with few persons trained, and/or 3) an absolute shortage of staff.

## How to Measure It

The number of TB treatment facilities with at least one health care professional trained in the previous 3 years is the numerator. The total number of facilities is the denominator. If no information is available at the administrative level, the number of

TB treatment facilities having at least one trained professional staff member during the monitoring visit is the numerator, and the total number of facilities visited is the denominator.

## Data Sources

- NTP training records
- Employee training certificates for BMUs reporting to NTP
- Facility training registers (where available)
- Interviews with staff members at facilities at various levels

## Frequency & Function

This indicator should be reported annually.

## Strengths & Limitations

Attendance at training courses is a relative measure, and training courses vary greatly in quality (and in duration, content, methodologies used, and skills evaluation). Attendance does not necessarily produce a care provider able to perform the key tasks listed in the respective job descriptions related to TB control. Furthermore, ability to perform does not automatically mean a change in practice to conform to the DOTS strategy. This emphasizes the need for detailed task analysis and specific (formal or informal) job descriptions. In addition, staff might have been trained but are not working in TB control (selection criteria of staff for training).

**Indicator 9.3**

# ADEQUATE STAFFING AT ALL LEVELS TO ENABLE IMPLEMENTATION OF DOTS

## Definition

Adequate staffing at all levels to enable implementation of DOTS. This is a yes/no indicator and should be answered separately for each level of the existing health system (i.e., central, regional, district, health facility, laboratory). This is a yes/no indicator.

## What It Measures

Both a yes and a no answer should be reviewed against data on outcome of activities (case detection and treatment outcome). If there is a perception that there is adequate staffing at one particular level, or all, but the outcome of activities is low, further assessment is needed to determine whether the staffing situation in reality is adequate and poor results are due to other reasons (like poor staff competence) or whether the staffing perception is incorrect. Inadequate human resources ranked first within the top five constraints to achieving global TB control targets in 17 of the 22 high-burden countries in 2003. This includes lack of skilled and/or motivated staff, inadequate distribution of staff, poor retention, and high turnover. The availability of sufficient staff (based on job descriptions and disease burden) is the foundation for reaching and sustaining the global TB control targets.

## How to Measure It

Data will be collected through record reviews, reviews of HR development plans, staffing monitoring, and interviews with staff and supervisors at all levels of the system. Supervisory reports should be reviewed, and routine information about staffing as well as job descriptions should be requested from relevant departments and units. Lists of tasks that can be used as a basis for assessment and interviews are included in Appendix F.

## Data Sources

- Staffing documents or rosters
- Interviews with staff members

## Frequency & Function

This indicator should be monitored at least once per year. After the baseline situation has been established, data collection is simplified.

## Strengths & Limitations

Although it is difficult to collect accurate data for this indicator, the perception of managers and care providers at different levels, in combination with the service outcome data, is essential in ongoing problem analysis for improving service delivery and ensuring quality control. To date, data for this indicator have usually not been the concern of the NTP, and program staff might therefore not fully appreciate the usefulness of the information despite its lack of accuracy.

# 10. Health Systems

## Introduction

A health system can be defined as a comprehensive network of public, private, parastatal, NGO, and informal sector providers and facilities. This includes all cadres of health workers and the financial, policy, and technical institutions and mechanisms that support providers and their health care facilities. The design and strengths of health systems are as diverse as the countries in which they function. As such, consideration for the context in which DOTS is being or can be delivered is a foundation for planning and implementing a sustainable, locally appropriate, and successful DOTS program.

The DOTS strategy includes technical and operational norms that have been successfully implemented through diverse health system structures—from community-based to highly specialized care structures. The DOTS strategy is designed to enhance the capacity of the primary health care network to detect, diagnose, treat, and cure TB patients. The implementation of quality TB control may strengthen the existing health system, particularly where it improves the referral networks between providers and laboratories, strengthens drug planning and management, and sharpens the focus on case management and successful treatment outcomes. Furthermore, DOTS expansion efforts are most effective where delivery strategies capitalize on the existing strengths of the health system, anticipate and adapt to changes in health system infrastructure or functions, and address health system constraints.

The monitoring indicators related to health systems are meant to support the identification of strengths within the health system that may be tapped into for DOTS delivery and to gauge the level of involvement of the TB control community with the wider health system. Particular emphasis is given to monitoring utilization of the forums and mechanisms used for policy development, budgeting, and planning in the health sector for the systematic contribution of TB control activities to broader health system priorities, and vice versa. These indicators highlight the needs at national and more decentralized levels for active collaboration between the TB control community and other health system partners.

The monitoring indicators related to health systems are of two types:

1. **Policy and planning**—that is, those that monitor the engagement of the national TB program with partners in the health system in terms of planning, including the following:

    a. TB control is highlighted as a priority within health sector plans (Indicator 3.1).

b. Budget is available and transparent for TB at all levels (Indicators 3.4 and 3.5).

c. TB program is represented in health services planning forums such as district health management committees, national health planning units, or their equivalents (Indicator 3.4).

d. TB benefits are included in national and community-level insurance schemes.

e. Anti-TB drugs are included in the essential drugs list.

f. TB control is integrated in the primary health care system (Indicators 3.1, 4.2, 5.1, and 9.3).

2. **Implementation**—that is, those that identify barriers or opportunities for DOTS implementation and expansion within the health system, including the following:

   a. TB control is included in monitoring or evaluation of overall PHC system performance.

   b. Percentage of health facilities that are involved in the DOTS network (e.g., percentage of public dispensaries that are stocked with anti-TB drugs and with staff equipped to deliver DOTS) is calculated (Indicators 6.7, 9.1, and 9.2).

   c. Percentage of health workers who have been trained in DOTS delivery is calculated (Indicators 3.9, 9.1, 9.2, and 9.3).

   d. Distribution of the beneficiaries of TB control services is similar to the estimated disease burden in the general population; notably, the gender, urban/rural, ethnic, and economic status of DOTS beneficiaries matches the estimated burden (Indicator 10.1).

### Indicator

- Equitable distribution of DOTS

## Resources

Evans T et al., eds. *Challenging inequities in health: from ethics to action*. New York, Oxford University Press, 2001.

Filmer D, Pritchett LH. Estimating wealth effects without expenditure data—or tears: an application to educational enrollments in states of India. *Demography*, 2001, 38(1):115–132.

Gwatkin DR. Health inequalities and the health of the poor: what do we know? What can we do? *Bulletin of the World Health Organization*, 2000, 78(1):3–18.

Hanson C. *Expanding DOTS in the context of a changing health system*. Geneva, World Health Organization, 2003 (WHO/CDS/TB/2003.318).

Pio A, Chaulet P. *Tuberculosis handbook*. Geneva, World Health Organization, 1998 (WHO/TB/98.253).

Ravallion M. *Poverty comparisons: a guide to concepts and methods*. Washington, DC, World Bank, 1992 (Living Standards Measurement Study, Working Paper No. 88).

Weil DE. Advancing tuberculosis control within reforming health systems. *International Journal of Tuberculosis and Lung Disease*, 2000, 4(7):597–605.

**Indicator 10.1**

# EQUITABLE DISTRIBUTION OF DOTS

## Definition

Percentage of TB patients notified under DOTS who represent specific subpopulations, namely 1) poor, 2) rural 3) ethnic groups, and 4) women,[1] relative to the percentage of the population accounted for by these subpopulations.

$$\frac{\text{Number of TB patients living in poverty}^{2}\text{ notified under DOTS in specified time period}}{\text{Total number of TB patients notified under DOTS in specified time period} \times \text{the percentage of the population living in poverty}} \times 100$$

Subpopulations 2, 3, and 4 can be substituted for subpopulation 1 in the above definition of numerator and denominator.

## What It Measures

The indicator measures the depth of DOTS coverage (i.e., the ability of the current DOTS delivery system to reach disadvantaged populations). The information is useful for identifying subpopulations that are not accessing DOTS proportionally, so that targeted interventions to reach these groups can be introduced. This indicator may reflect general strengths or limitations of the primary health care network in serving the population. Monitoring of this indicator over time will enable consideration of the appropriateness of DOTS delivery mechanisms for various subpopulations and will also facilitate the identification in possible changes in TB epidemiology (e.g., increase in the percentage of TB patients who are women, linked to the disproportionate number of women infected with HIV). Few countries have reached the global target of detection of at least 70% of estimated cases. It is frequently not well understood who the "missing" cases are. This indicator will help to identify subpopulations that contribute to the cases not reported. Monitoring of this indicator also affords an opportunity to evaluate whom is receiving public subsidies for TB control.

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[1] Historically, the incidence of TB has been higher among men than women, so equality in case notifications may not be expected. However, in many countries with high HIV prevalence, the gender balance is shifting and is approaching a 1:1 ratio. Measuring the distribution of DOTS between men and women must be done in the context of the local epidemiology.

[2] Definitions of poverty may be country specific, and the classification of patients into "wealth categories" may require special surveys. Detailed information on measuring poverty is available on the Internet at http://www.worldbank.org/poverty/health/index.htm.

## How to Measure It

The numerator is the total number of TB patients from a specified subpopulation notified under DOTS. Among data on the four subpopulations included in this indicator, only gender data are routinely collected. Additional data must be collected from patients during routine visits or as part of a special survey to enable analysis of the proportion of poor, rural, and ethnic groups accessing TB services.

## Data Sources

- Quarterly reports on TB case registration
- Census statistics
- Special surveys

## Frequency & Function

This indicator should be measured annually.

## Strengths & Limitations

This indicator allows for a more in-depth evaluation of DOTS coverage in a population and may help to identify subpopulations not being reached by DOTS. Without TB disease prevalence data disaggregated by these subpopulations, the indicator assumes equal distribution of TB in the population and therefore may underestimate underrepresentation of some marginalized populations that, in fact, have a higher prevalence of disease. The indicator relies on the collection of data not routinely collected or reported.

# APPENDIX A: CHECKLIST OF FEATURES OF A GOOD MONITORING AND EVALUATION SYSTEM

The following checklist is a summary of the key elements of a good M&E system.

| M&E UNIT |
|---|
| ❑ A unit or individual within the central unit of the program who is responsible for M&E |
| ❑ A significant contribution to the national M&E budget |
| ❑ A formalized (M&E) link with national and local research institutions, professional associations, and academic institutions |
| ❑ A formalized (M&E) link with leading NGOs, donors, and community-based organizations |
| ❑ Epidemiologist and/or social science expertise in the M&E unit or affiliated with the unit |
| ❑ Data processing and statistical expertise in the M&E unit or affiliated with the unit |
| ❑ Data dissemination expertise in the M&E unit or affiliated with the unit |
| **Clear Goals** |
| ❑ Well-defined national program goals and targets |
| ❑ Regular reviews/evaluations of the progress of the implementation of the national program plans |
| ❑ Guidelines and guidance to districts and regions or provinces for M&E |
| ❑ Guidelines for linking M&E to other sectors |
| ❑ Coordination of national and donor M&E needs |
| **Indicators** |
| ❑ A set of priority indicators and additional indicators at different levels of M&E, some of which are comparable over time and with other countries |
| **Data Collection, Analysis, and Use** |
| ❑ An overall national data collection and analysis plan |
| ❑ A plan to collect data and analyze indicators at different levels of M&E |
| ❑ Systemwide knowledge and capacity (e.g., tools and budget) to collect and use data |
| ❑ A plan to supervise, support, and ensure the quality of data collection |
| ❑ A plan to ensure the translation of data into problem identification, strategic planning, policy formulation, etc. |
| **Data Dissemination** |
| ❑ An overall national data dissemination plan |
| ❑ A well-disseminated informative annual report of the M&E unit |
| ❑ Annual meeting to disseminate and discuss M&E and research findings with policy-makers and planners |
| ❑ A clearinghouse for generation and dissemination of findings |
| ❑ A centralized database or library of all data collection, including ongoing research |
| ❑ Coordination of national and donor M&E dissemination needs |

Reference—*National AIDS programme: a guide to monitoring and evaluation*. Geneva, Joint United Nations Programme on HIV/AIDS (UNAIDS), 2000 (UNAIDS/00.17E).

# APPENDIX B: SOURCES OF TUBERCULOSIS DATA—STANDARDIZED TUBERCULOSIS DATA COLLECTION TOOLS AND REPORTS

There are a number of standardized forms and registers that are recommended for effective TB case management. The forms and registered listed in this section are those mentioned in this compendium as sources of data; this section is not an exhaustive list of all recommended forms and registers. A complete set of forms can be found in the TB handbook.[1]

## 1. Forms and Registers at the Peripheral Treatment Unit (Health Post, Health Center, Under the Supervision of the BMU)

### TB Laboratory Form: Request for Sputum Examination

A request for sputum examination form is completed when the initial sputum sample is obtained from a pulmonary TB suspect (e.g., someone who presents to a general health facility and has been coughing for more than 3 weeks). The health worker should register complete address information on the form so that if the smear is positive and the patient does not return for treatment, the person can be traced. Registering whether the examination is for diagnosis or follow-up is essential since the same form is used for both purposes. The laboratory technician who examines the sputum should complete the results section of the sputum examination form and fill in the laboratory serial number.

### Tuberculosis Treatment Card

A TB treatment card is started for every patient diagnosed with TB of any category (e.g., new smear positive, new smear negative, extrapulmonary, relapse, treatment after default) or transferred in from another health facility. The TB treatment card includes information on the patient (e.g., name, address, sex, age) as well as pertinent information on the prescribed regimen and drug dosages. Great care should be taken to ensure that the information on the TB treatment card is accurate, since it is crucial to notification of cases and evaluation of treatment outcomes and is the basis of the district TB register.

### Register of TB Suspects

The register of TB suspects, sometimes known as the "cough register," records all of the respiratory symptomatic patients classified as TB suspects. It is particularly useful for health facilities without microscopy, which must monitor sputa sent to other laboratories. It is also useful for evaluating the prevalence of TB suspects at first-level health facilities and referral of suspects for microscopy and estimating the supplies needed for bacteriological examinations. The registry records information on the

[1] Pio A, Chaulet P. *Tuberculosis handbook*. Geneva, World Health Organization, 1998 (WHO/TB/98.253).

patient (e.g., name, age, sex, address), date the sputum was sent to a laboratory, the results, and observations/clinician's diagnosis.

## TB LABORATORY FORM
## REQUEST FOR SPUTUM EXAMINATION

Name of health facility _____ Date _____

Name of patient _____ Age _____ Sex: M ❒ F ❒

Complete address _____

_____ District _____

Reason for examination:

Diagnosis ❒ TB Suspect No. _____

OR Follow-up ❒ Patient's District TB No.* _____

Disease site: Pulmonary ❒ Extrapulmonary ❒ (specify)_____

Number of sputum samples sent with this form _____

Date of collection of first sample _____ Signature of specimen collector _____

* *Be sure to enter the patient's District TB No. for follow-up of patients on TB treatment.*

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## RESULTS (TO BE COMPLETED BY LABORATORY)

Lab. Serial No. _____

(a) Visual appearance of sputum:

Mucopurulent ☐ Blood-stained ☐ Saliva ☐

(b) Microscopy:

| Date | Specimen | Results | Positive (grading) | | | |
|---|---|---|---|---|---|---|
| | | | +++ | ++ | + | scanty (1–9) |
| | 1 | | ☐ | ☐ | ☐ | ☐ |
| | 2 | | ☐ | ☐ | ☐ | ☐ |
| | 3 | | ☐ | ☐ | ☐ | ☐ |

Date _____ Examined by (Signature) _____

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The completed form (with results) should be sent to the health facility and to the District Tuberculosis Unit.

## TUBERCULOSIS TREATMENT CARD

Name _____ District TB No. _____

Complete address _____ Health facility _____

Sex: M ❑ F ❑ Age _____

Name and address of community treatment supporter (if applicable) _____

_____

**Disease site**

Pulmonary ❑ Extrapulmonary ❑ (specify) _____

**Type of patient**

New ❑ Treatment after failure ❑
Relapse ❑ Treatment after default ❑
Transfer in ❑ Other (specify) ❑ _____

**I. INITIAL PHASE — Prescribed regimen and dosages**

**Tick frequency:** Daily ❑ 3 times/week ❑

***Tick category and indicate number of tablets per dose and dosage of S (grams):***

**CAT I**
New case ❑
(smear-positive, or seriously ill smear-negative, or EP)
HR Z E [S]

**CAT II**
Re-treatment ❑
HR Z E S

**CAT III**
New case ❑
(smear-negative or EP)
HR Z E

**CAT IV**
Chronic or MDR-TB ❑

HR: isoniazid and rifampicin Z: pyrazinamide E: ethambutol S: streptomycin

| Results of sputum examination | | | | Weight (kg) |
|---|---|---|---|---|
| Month | Date | Smear | Lab. No. | |
| 0 | | | | |
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**Tick appropriate box after the drugs have been administered**

| MONTH \ DAY | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | Number doses this month | Total number doses given |
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**Drugs given to supporter**

| DATE | DOSES |
|---|---|
| | |
| | |
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| | |
| | |

Please turn over for continuation phase

# TUBERCULOSIS TREATMENT CARD

**II. CONTINUATION PHASE — Prescribed regimen and dosages**

**Tick frequency:** Daily ❑ 3 times/week ❑

| **Tick category:** | **CAT I** | **CAT II** | **CAT III** | **CAT IV** |
|---|---|---|---|---|
| | New case ❑ (smear-positive, or seriously ill smear-negative or EP) | Re-treatment ❑ | New case ❑ (smear-negative or EP) | Chronic or MDR-TB ❑ |
| **Indicate number of tablets per dose:** | ☐ (4 months) HR or ☐ (6 months) HE | ☐☐ (5 months) HR E | ☐ (4 months) HR or ☐ (6 months) HE | ☐☐☐☐ |

| MONTH \ DAY | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | Number doses this month | Total number doses given |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
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Enter ✔ on day of directly observed treatment. For a self-administered regimen, enter **X** on day when drugs are collected. Any time drugs are given for self-administration, draw a horizontal line ( ——— ) through the number of days' supply given.

**Observations:**

_____

_____

_____

_____

**Name and address of contact person** _____

**Treatment outcome**

Date of decision _____

Cure ❑
Treatment completed ❑
Treatment failure ❑
Died ❑
Default ❑
Transfer out ❑

## REGISTER OF TB SUSPECTS

Year _____ Facility _____

| Date | TB Suspect Number | Name of TB Suspect | Age M | Age F | Complete Address | Date Sputum Sent to Lab | Date Results Received | Results of Sputum Examinations 1 | 2 | 3 | TB Treatment Card Opened? (record date) | Observations/ Clinician's Diagnosis |
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## 2. Recording and Reporting Forms—Basic Management Unit (i.e., District Level)

### District Tuberculosis Register

Every patient in the district who starts treatment must be registered in the district TB register. All information included on the TB treatment card (or in the TB treatment register at the health facility) is copied into the district TB register. There is no separate form for transferring the information from the facility to the district register. A health worker at a facility either sends or brings the information to the district level each month, or a district TB coordinator collects the information during a supervisory visit to the health facility at least once a quarter. The district TB register records information on the patient, the disease site (pulmonary or extrapulmonary), and the patient's category (i.e., new case, relapse, treatment after failure, treatment after default, transfer in, and other). The register is also used to record information on the sputum-smear examination carried out at the start and during treatment follow-up, for monitoring the progress of the district in achieving at least an 85% treatment success rate. The register should include one of six possible treatment outcomes—cure, treatment completion, failure, death, default, or transfer out—for each patient. Information from the district TB register is used to complete the quarterly reports for cohort analysis and program management.

### Quarterly Report on Treatment Outcomes

This is a key report providing information for analyzing treatment outcomes and measuring the treatment indicators of the NTP. This process is often referred to as a cohort analysis. The district TB coordinator compiles the report using information contained in the district TB. The box in the top right of the form should specify the quarter of the year when the cases were registered, which will have ended 12 months before the date when the report is completed.

The treatment outcomes of new pulmonary TB cases, divided into smear-positive and smear-negative cases, are recorded in the middle of the form. The total male and female cases are taken from the quarterly report on TB case registration completed 12 months earlier for that particular quarter. The lower part of the form is for recording information on relapse pulmonary cases and other retreatment cases (e.g., treatment-after-failure and treatment-after-default cases). The district TB coordinator submits the report to the regional TB coordinator so that it can be analyzed and checked for consistency and completeness.

## Quarterly Report on TB Case Registration

The district quarterly report on TB case registration should meet the epidemiological and administrative requirements for the notification of new and previously treated cases diagnosed in the previous quarter. Prepared by the district TB coordinator, this report is based on the information entered in the district TB register. It provides the total number of new pulmonary smear-positive and pulmonary smear-negative cases and new extrapulmonary cases by age group that were diagnosed and registered during a quarter for a particular district (Block 1). The new pulmonary smear-positive cases are classified according to age and sex (Block 2). Previously treated smear-positive cases are classified according to whether they were relapse, treatment after failure, treatment after default, or other. The report is submitted to the regional TB coordinator, who analyzes the data it contains and reviews the report for consistency. The regional TB coordinator is responsible for sending the quarterly report from each district to the TB central unit.

## DISTRICT TUBERCULOSIS REGISTER—LEFT SIDE OF THE REGISTER BOOK

| Date of Regis-tration | District TB No. | Name | Sex M/F | Age | Complete Address | Health Facility | Date Treatment Started | Treatment Category* | Disease Site P/EP | Type of Patient** | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | N | R | F | D | T | O |
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***Enter the treatment category:**

**CAT I:** New smear-positive case, or
New case (seriously ill smear-negative
or seriously ill EP), e.g., $2(HRZE)/4(HR)_3$

**CAT II:** Re-treatment, e.g., $2(HRZES)/1HRZE/5(HR)_3E_3$

**CAT III:** New case (smear-negative or EP), e.g., $2(HRZ)/4(HR)_3$

****Enter only one code:**

**N**: **New** – A patient who has never had treatment for TB or who has taken anti-TB drugs for less than 1 month
**R**: **Relapse** – A patient previously treated for tuberculosis who has been declared cured or treatment completed, and is diagnosed with bacteriologically positive (smear or culture)TB
**F**: **Treatment after failure** – A patient who is started on a re-treatment regimen after having failed previous treatment
**D**: **Treatment after default** – A patient who returns to treatment, positive bacteriologically, following interruption of treatment for 2 months or more
**T**: **Transfer in** – A patient who has been transferred from another TB register to continue treatment
**O**: **Other** – All cases that do not fit the above definitions. (This group includes **chronic case**, a patient who is sputum positive at the end of a re-treatment regimen.)

## DISTRICT TUBERCULOSIS REGISTER—RIGHT SIDE OF THE REGISTER BOOK

| Results of Sputum Examination | | | | | | | | | | | | Outcome of Treatment and Date †† | | | | | | Remarks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Before treatment | | | 2 or 3 months † | | | 5 months | | | End of treatment | | | Cure | Com-pleted | Failure | Died | Default | Transfer out | |
| Date | Result | Lab No. | Date | Result | Lab No. | Date | Result | Lab No. | Date | Result | Lab No. | | | | | | | |
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† CAT I patients have follow-up sputum examination at 2 months; CAT II patients have follow-up sputum examination at 3 months.

**†† Enter date in the appropriate column:**

**Cure**……Sputum smear-positive patient who is sputum smear-negative in the last month of treatment and on at least one previous occasion

**Treatment completed**…….Patient who has completed treatment but who does not meet the criteria to be classified as a cure or failure

**Treatment failure**……Patient who is sputum smear-positive at 5 months or later during treatment *(also a patient who was initially smear-negative and became smear-positive at 2 months)*

**Died**……Patient who dies for any reason during the course of treatment

**Default**……...Patient whose treatment was interrupted for 2 consecutive months or more

**Transfer out**…Patient who has been transferred to another recording and reporting unit and for whom treatment outcome is not known

# QUARTERLY REPORT ON TREATMENT OUTCOMES

| Name of district:_____ | *Name of District TB Coordinator:*_____ | **Patients registered during**_____ **quarter of year** _____***** |
|---|---|---|
| District no.:_____ | Signature: _____ | Date of completion of this form: _____ |

| ***Type of case*** | | ***Total number of pulmonary patients registered during the quarter reported on ***** | **Treatment outcomes** | | | | | | ***Total number evaluated for outcomes: Sum of columns 1 to 6*** |
|---|---|---|---|---|---|---|---|---|---|
| | | | Cure (1) | Treatment Completed (2) | Died (3) | Treatment failure (4) | Default (5) | Transfer out (and outcome unknown) (6) | |
| **1. New** | 1.1 Smear (+) | | | | | | | | |
| | 1.2 Smear (–) | | | | | | | | |
| **2. Smear positive*** Re-treatment** | 2.1 Relapses | | | | | | | | |
| | 2.2 Treatment after failure | | | | | | | | |
| | 2.3 Treatment after default | | | | | | | | |

* Quarter: This form applies to patients registered (recorded in the District Tuberculosis Register) in the quarter that ended 12 months ago. For example, if completing this form at the beginning of the 3rd quarter, record data on patients registered in the 2nd quarter of the previous year.

** These numbers are transferred from the *Quarterly Report on TB Case Registration* for the above quarter. Of these patients, _____ (number) were excluded from evaluation for the following reasons: _____

*** In areas routinely using culture, a separate form for culture-positive patients should be used.

# QUARTERLY REPORT ON TB CASE REGISTRATION

| | |
|---|---|
| Name of district: _____<br>***District no.:*** _____<br>***Name of District TB Coordinator:*** _____<br>Signature: _____ | **Patients registered during** _____ ***quarter of year***_____<br><br>Date of completion of this form: _____ |

**BLOCK 1. NEW CASES**

| NEW | Pulmonary | | | Extrapulmonary (3) | | Total (4) |
|---|---|---|---|---|---|---|
| | Smear (+) (1) | Smear (–) (2) | | | | |
| | | <15 years | ≥15 years | <15 years | ≥15 years | |
| | | | | | | |

**BLOCK 2. NEW PULMONARY SMEAR (+) CASES ONLY, FROM BLOCK 1 ABOVE, BY SEX AND AGE GROUP**

| | Age Group In Years | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Sex** | 0-14 | 15-24 | 25-34 | 35-44 | 45-54 | 55-64 | ≥65 | TOTAL |
| M | | | | | | | | |
| F | | | | | | | | |

**BLOCK 3. PREVIOUSLY TREATED CASES (SMEAR POSITIVE)***

| Relapse | Treatment after failure | Treatment after default | Other |
|---|---|---|---|
| | | | |

* In areas routinely using culture, a separate form for reporting culture-positive patients should be used.

## 3. Laboratory Recording Forms—Microscopy Unit

### Tuberculosis Laboratory Register

All laboratories (governmental, private, and NGO) involved in TB should use the TB laboratory register to record the information for each individual patient who submitted a sputum sample for diagnosis or for treatment follow-up. The register is a means of informing the laboratory technicians and the TB program managers of the number of suspects examined, the number of smear-positive cases detected, and the number and results of smear examination for treatment follow-up. Additionally, it can be used as a cross-reference for identifying patients who have not been registered in the district TB register and who may or may not be receiving treatment.

## TUBERCULOSIS LABORATORY REGISTER

| Lab serial no. | Date | Name (in full) | Sex M/F | Age | Complete address (for new patients) | Name of referring health facility | Reason for examination[a] | | Microscopy results | | | Remarks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Diagnosis | Follow-up | 1 | 2 | 3 | |
| | | | | | | | | | | | | |
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[a] If sputum is for diagnosis, write a tick under Diagnosis. If sputum is for follow-up, write the patient's District TB number under Follow-up.

# APPENDIX C: TB DOTS INDICATORS BY FUNCTION

The following table organizes the indicators presented in the compendium by function: whether you would use the indicator for routine reporting (I), process evaluation/monitoring (II), program review/impact evaluation (III), or special survey (IV). This table may be useful in planning the collection, analysis, and use of results.

| Indicator by Function | |
|---|---|
| **I. Routine reporting (quarterly and/or annually)** | |
| 1.1 | TB case detection rate |
| 1.2 | Treatment success rate |
| 1.3 | DOTS coverage |
| 1.5 | HIV seroprevalence among TB patients |
| 2.1 | Case notification rate |
| 2.2 | Case notification rate—new smear-positive pulmonary TB cases |
| 2.3 | New pulmonary TB cases with no smear result |
| 2.4 | New adult smear-positive cases |
| 2.5 | Retreatment TB cases |
| 2.6 | New extrapulmonary TB cases |
| 2.7 | New TB cases with no smear conversion result |
| 2.8 | Sputum conversion rate at the end of the initial phase of treatment |
| 2.9 | Cure rate |
| 2.10 | Treatment completion rate |
| 2.11 | Death rate |
| 2.12 | Treatment failure rate |
| 2.13 | Default rate |
| 2.14 | Transfer-out rate |
| 2.15 | Retreatment failure rate (chronic TB rate) |
| 4.3 | TB microscopy units with adequate workloads |
| 4.5 | TB suspects who are smear positive |
| 4.6 | Smear-negative cases properly diagnosed |
| 7.1 | Completeness of reporting to NTP |
| **II. Process evaluation/monitoring (every 6 months and/or annually)** | |
| 1.1 | TB case detection rate |

| Indicator by Function | |
|---|---|
| 1.2 | Treatment success rate |
| 1.3 | DOTS coverage |
| 1.5 | HIV seroprevalence among TB patients |
| 2.1 | Case notification rate |
| 2.2 | Case notification rate—new smear-positive pulmonary TB cases |
| 2.3 | New pulmonary TB cases with no smear result |
| 2.4 | New adult smear-positive cases |
| 2.5 | Retreatment TB cases |
| 2.6 | New extrapulmonary TB cases |
| 2.7 | New TB cases with no smear conversion result |
| 2.8 | Sputum conversion rate at the end of the initial phase of treatment |
| 2.9 | Cure rate |
| 2.10 | Treatment completion rate |
| 2.11 | Death rate |
| 2.12 | Treatment failure rate |
| 2.13 | Default rate |
| 2.14 | Transfer-out rate |
| 2.15 | Retreatment failure rate (chronic TB rate) |
| 3.1 | TB control is among stated priorities |
| 3.2 | National TB policy |
| 3.3 | National TB program manual |
| 3.4 | NTP medium-term development plan and budget |
| 3.5 | NTP annual work plan and budget |
| 3.6 | Peripheral units with work plan and budget |
| 3.7 | Financial resources committed to NTP from the government |
| 3.8 | Annual NTP budget allocated to implement DOTS as required by medium-term development plan |
| 3.9 | Key NTP staff positions filled |
| 3.10 | Interinstitutional coordination of TB control |
| 3.11 | Existence and dissemination of NTP annual report |
| 3.12 | National TB control policy addresses links between TB and HIV |

| Indicator by Function | |
|---|---|
| 4.1 | Existence of comprehensive laboratory network |
| 4.3 | TB microscopy units with adequate workloads |
| 4.4 | TB microscopy units submitting slides for rechecking |
| 4.5 | TB suspects who are smear positive |
| 4.6 | Smear-negative cases properly diagnosed |
| 4.7 | Detected smear-positive cases registered for treatment (inverse of primary default rate) |
| 5.1 | Patients under direct observation of therapy |
| 5.2 | New TB patients who were prescribed the correct regimen |
| 6.1 | Existence of a quality assurance system for drug management |
| 6.2 | Anti-TB drugs meeting international minimum quality standards |
| 6.3 | Existence of buffer stock at central, regional, or district-level facility |
| 6.4 | Accuracy of stock records for anti-TB drugs |
| 6.5 | Time anti-TB drugs are out of stock—storage facilities |
| 6.6 | Time anti-TB drugs are out of stock—treatment facilities |
| 6.7 | Basic management units where anti-TB drugs are available |
| 6.8 | Anti-TB drug samples that fail quality control tests |
| 7.1 | Completeness of reporting to NTP |
| 7.2 | Accuracy of reporting to NTP |
| 8.1 | Supervision of DOTS implementation |
| 8.2 | Existence of supervision guidelines |
| 9.1 | TB microscopy units with at least one laboratory technician trained in AFB microscopy |
| 9.2 | Health care units with at least one health care professional trained in TB case detection and treatment |
| 9.3 | Adequate staffing at all levels to enable implementation of DOTS |
| 10.1 | Equitable distribution of DOTS |
| **III. Program review/impact evaluation (every 2–5 years)** | |
| 1.1 | TB case detection rate |
| 1.2 | Treatment success rate |
| 1.3 | DOTS coverage |
| 1.4 | Surveillance of multidrug-resistant TB |
| 1.5 | HIV seroprevalence among TB patients |

| Indicator by Function | |
|---|---|
| 2.1 | Case notification rate |
| 2.2 | Case notification rate—new smear-positive pulmonary TB cases |
| 2.3 | New pulmonary TB cases with no smear result |
| 2.4 | New adult smear-positive cases |
| 2.5 | Retreatment TB cases |
| 2.6 | New extrapulmonary TB cases |
| 2.7 | New TB cases with no smear conversion result |
| 2.8 | Sputum conversion rate at the end of the initial phase of treatment |
| 2.9 | Cure rate |
| 2.10 | Treatment completion rate |
| 2.11 | Death rate |
| 2.12 | Treatment failure rate |
| 2.13 | Default rate |
| 2.14 | Transfer-out rate |
| 2.15 | Retreatment failure rate (chronic TB rate) |
| 3.1 | TB control is among stated priorities |
| 3.2 | National TB policy |
| 3.3 | National TB program manual |
| 3.4 | NTP medium-term development plan and budget |
| 3.5 | NTP annual work plan and budget |
| 3.6 | Peripheral units with work plan and budget |
| 3.8 | Annual NTP budget allocated to implement DOTS as required by medium-term development plan |
| 3.9 | Key NTP staff positions filled |
| 3.10 | Interinstitutional coordination of TB control |
| 3.11 | Existence and dissemination of NTP annual report |
| 3.12 | National TB control policy addresses links between TB and HIV |
| 4.1 | Existence of comprehensive laboratory network |
| 4.2 | TB microscopy coverage |
| 4.3 | TB microscopy units with adequate workloads |
| 4.4 | TB microscopy units submitting slides for rechecking |

| Indicator by Function | |
|---|---|
| 4.5 | TB suspects who are smear positive |
| 4.6 | Smear-negative cases properly diagnosed |
| 4.7 | Detected smear-positive cases registered for treatment (inverse of primary default rate) |
| 5.1 | Patients under direct observation of therapy |
| 5.2 | New TB patients who were prescribed the correct regimen |
| 6.1 | Existence of a quality assurance system for drug management |
| 6.2 | Anti-TB drugs meeting international minimum quality standards |
| 6.3 | Existence of buffer stock at central, regional, or district-level facility |
| 6.4 | Accuracy of stock records for anti-TB drugs |
| 6.5 | Time anti-TB drugs are out of stock—storage facilities |
| 6.6 | Time anti-TB drugs are out of stock—treatment facilities |
| 6.7 | Basic management units where anti-TB drugs are available |
| 6.8 | Anti-TB drug samples that fail quality control tests |
| 7.1 | Completeness of reporting to NTP |
| 7.2 | Accuracy of reporting to NTP |
| 8.2 | Existence of supervision guidelines |
| 9.1 | TB microscopy units with at least one laboratory technician trained in AFB microscopy |
| 9.2 | Health care units with at least one health care professional trained in TB case detection and treatment |
| **IV. Special survey (periodic)** | |
| 1.1 | TB case detection rate |
| 1.2 | Treatment success rate |
| 1.4 | Surveillance of multidrug-resistant TB |
| 4.2 | TB microscopy coverage |
| 5.1 | Patients under direct observation of therapy |
| 5.2 | New TB patients who were prescribed the correct regimen |
| 10.1 | Equitable distribution of DOTS |

# APPENDIX D: KEY TB CONTROL INDICATORS

The following table includes a list of key TB control indicators that make up a minimum set of M&E indicators for assessing the performance of an NTP. Many of these indicators are process-level indicators that measure the development and implementation of the expanded DOTS strategy as well as important program outcomes.

| Key TB Control Indicators |
|---|
| **Indicators for Global Reporting** |
| 1.1 TB case detection rate |
| 1.2 Treatment success rate |
| 1.3 DOTS coverage |
| 1.4 Surveillance of multidrug-resistant TB |
| 1.5 HIV seroprevalence among TB patients |
| **Indicators for Program Outcomes** |
| 2.4 New adult smear-positive cases |
| **Political Commitment** |
| 3.2 National TB policy |
| 3.3 National TB program manual |
| 3.4 NTP medium-term development plan and budget |
| 3.5 NTP annual work plan and budget |
| 3.12 National TB control policy addresses links between TB and HIV |
| **Diagnosis and Laboratories** |
| 4.1 Existence of comprehensive laboratory network |
| 4.4 TB microscopy units submitting slides for rechecking |
| **Case Management and Treatment** |
| 5.1 Patients under direct observation of therapy |
| **Drug Management** |
| 6.1 Existence of a quality assurance system for drug management |
| 6.2 Anti-TB drugs meeting international minimum quality standards |
| 6.3 Existence of buffer stock at central, regional, or district-level facility |
| **Recording and Reporting** |
| 7.1 Completeness of reporting to NTP |
| **Supervision** |
| 8.1 Supervision of DOTS implementation |
| 8.2 Existence of supervision guidelines |

| Key TB Control Indicators | |
|---|---|
| **Human Resources Development** | |
| 9.1 | TB microscopy units with at least one laboratory technician trained in AFB microscopy |
| 9.2 | Health care units with at least one health care professional trained in TB case detection and treatment |
| **Health Systems** | |
| 10.1 | Equitable distribution of DOTS |

# APPENDIX E: MODEL BATCH CERTIFICATE

## General Instructions

Please refer to the explanatory notes below for full instructions on how to complete this form and information on the implementation of the scheme. These forms are suitable for generation by computer. They should always be submitted as a hard copy, with responses printed in type rather than handwritten. Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

| Manufacturer's/Official[1] Batch Certificate of a Pharmaceutical Product | |
|---|---|
| This certificate conforms to the format recommended by the World Health Organization | |
| 1. | No. of certificate: |
| 2. | Importing (requesting) authority: |
| 3. | Name of product:[2] |
| 3.1. | Dosage form: |
| 3.2. | Active ingredient(s) and amount(s) per unit dose: |
| 3.2.1. | Is the composition of the product identical to that registered in the country of export? yes/no/not applicable[3] (*key in as appropriate*) If no, please attach formula (including excipients) of both products. |
| 4. | Product license holder[4] (name and address): |
| 4.1. | Product license number:[4] |
| 4.2. | Date of issue:[4] |
| 4.3. | Product license issued by:[4] |
| 4.4. | Product certificate number:[4,5] |
| 5.1. | Batch number: |
| 5.2. | Date of manufacture: |
| 5.3. | Shelf life (years): |
| 5.4. | Contents of container: |
| 5.5. | Nature of primary container: |
| 5.6. | Nature of secondary container/wrapping: |
| 5.7. | Specific storage conditions: |
| 5.8. | Temperature range: |
| 6. | Remarks:[6] |
| 7. | Quality analysis: |
| 7.1. | What specifications apply to this dosage form? Either specify the pharmacopoeia or append company specifications.[7] |
| 7.1.1. | In the case of a product registered in the exporting country, have these company specifications[7] been accepted by the competent authority? yes/no *(key in as appropriate)* |
| 7.2. | Does the batch comply with all parts of the above specifications? yes/no *(key in as appropriate)* |
| 7.3. | Append certificate of analysis.[8] |

| |
|---|
| It is hereby certified that the above declarations are correct and that the results of the analyses and assays on which they are based will be provided on request to the competent authorities in both the importing and exporting countries. |
| Name and address of authorized person: |
| Telephone number: Fax number: |
| Signature of authorized person: |
| Stamp and date: |

## Explanatory Notes

Certification of individual batches of a pharmaceutical product is only undertaken exceptionally by the competent authority of the exporting country. Even then, it is rarely applied other than to vaccines, sera, and biological products. For other products, the responsibility for any requirement to provide batch certificates rests with the product license holder in the exporting country. The responsibility to forward certificates to the competent authority in the importing country is most conveniently assigned to the importing agent. Any inquiries or complaints regarding a batch certificate should always be addressed to the competent authority in the exporting country. A copy should be sent to the product license holder.

[1] Strike out whichever does not apply.

[2] Use, whenever possible, international nonproprietary names (INNs) or national nonproprietary names.

[3] "Not applicable" means that the product is not registered in the country of export.

[4] All items under 4 refer to the product license or the certificate of a pharmaceutical product issued in the exporting country.

[5] This refers to the certificate of a pharmaceutical product as recommended by the World Health Organization.

[6] Indicate any special storage conditions recommended for the product as supplied.

[7] For each of the parameters to be measured, specifications give the values that have been accepted for batch release at the time of product registration.

[8] Identify and explain any discrepancies from specifications. Government batch release certificates issued by certain governmental authorities for specific biological products provide additional confirmation that a given batch has been released, without necessarily giving the results of testing. The testing results are contained in the manufacturer's certificate of analysis.

# APPENDIX F: HUMAN RESOURCE DEVELOPMENT ASSESSMENT FORMS

The following assessment forms pertain to Indicator 3.9 (for district, regional, and central levels) and Indicator 9.3. A full description of the HR country assessment is available in work by Bergstrom and Plamer.[1]

*Instructions for filling in assessment forms 1 through 4*

## Assessment Form 1

Follow the steps below to assess the needs for different types and numbers of staff at **peripheral-level** government health facilities:

- Determine the major tasks to be performed at peripheral-level government health facilities (This will most likely be limited to three major tasks, namely, detection, diagnosis, and treatment of a TB patient.)
- Estimate time needed to perform each of these tasks
- Determine which type of staff is performing each task
- Determine the existing type and number of the staff implementing the tasks at peripheral-level government health facilities
- Determine the workload on the basis of the number of patients diagnosed
- Determine the current work time available for all patient care, and then the work time dedicated to TB control, for each type of staff at peripheral-level government health facilities (specialized/multipurpose staff)
- Determine discrepancy, if any, between available staff and required staff if 70% case detection were achieved.

Assessment form 1 consists of four columns. The first column lists the task being assessed; the second column provides an estimate of time needed; the third column provides space for the country-specific estimate, which may or may not differ from the estimate shown in the second column; and the last column provides space for listing the type of staff performing the task.

[1] Bergstrom K, Plamer K. *Questionnaire to assess the current staffing situation and future staff needs for TB control in high burden countries*. Geneva, Stop TB Department, World Health Organization, March 2003.

## Assessment Form 2

Use the core tasks listed below to assess the staff needs at the **district level.** There should be sufficient staff capacity to coordinate all of the following core tasks of DOTS implementation:

- Prepare decentralized strategic plans for TB control
- Manage budgets and finances
- Plan and manage drug supplies and equipment
- Maintain treatment registers
- Conduct supervisory visits
- Ensure that lower level staff are competent to implement TB control services
- Monitor DOTS implementation
- Support laboratory services
- Coordinate advocacy activities
- Coordinate activities with partners.

Assessment form 2 consists of three columns. The first column lists the core tasks as indicated above, the second column provides space for noting who is currently responsible for implementing each core task, and the third column provides space for listing the number of additional staff members needed for each task. Space is provided below the columns for describing why staff members are needed.

## Assessment Form 3

Use the core tasks listed below to assess the staff needs at the **regional level.** There should be sufficient staff capacity to coordinate all of the following core tasks of DOTS implementation:

- Prepare decentralized strategic plans for TB control
- Manage budgets and finances
- Plan and manage drug supplies and equipment
- Conduct supervisory visits
- Ensure that lower level staff are competent to implement TB control services
- Monitor DOTS implementation
- Support laboratory services
- Coordinate advocacy activities
- Coordinate activities with partners.

Assessment form 3 consists of three columns. The first column lists the core tasks as indicated above, the second column provides space for noting who is currently responsible for implementing each core task, and the third column provides space for listing the number of additional staff members needed for each task. Space is provided below the columns for describing why staff members are needed.

## Assessment Form 4

Use the core tasks listed below to assess staff capacity and need at the **central level**. In high-burden countries, dedicated staff members are generally needed for all of the areas listed. There should be sufficient staff capacity to coordinate all of the following core tasks of DOTS implementation:

- Strategic planning, including policy framework and donor coordination
- Financing
- Human resource development
- Drug management
- Technical support to regions and districts
- Coordination with laboratory services
- Monitoring and evaluation
- IEC
- Advocacy
- Operational research
- Intersectoral collaboration and coordination.

Assessment form 4 consists of three columns. The first column lists the core tasks as indicated above, the second column provides space for noting who is currently responsible for implementing each task, and the third column provides space for listing the number of additional staff members needed for each task. Space is provided below the columns for describing why staff members are needed.

## ASSESSMENT FORM 1

Use this worksheet to calculate time estimates for treatment of one new sputum smear-positive tuberculosis patient (Indicator 9.3)

| Task | General estimate of time needed | Your estimate of time needed | Type of staff performing task in country |
|---|---|---|---|
| 1. First visit to outpatient, patient suspected of having TB, smear examination | 15 min | | |
| 2. Second visit, diagnosis confirmed, patient started on treatment | 15 min | | |
| 3. Initial phase, 56 doses of observed treatment | 56 × 5 min = 280 min | | |
| 4. Visit for first follow-up sputum examination | 10 min | | |
| 5. Continuation phase, 48 doses of observed treatment | 48 × 5 min = 240 min | | |
| 6. Visit for second follow-up sputum examination | 10 min | | |
| 7. Visit for third follow-up sputum examination | 10 min | | |
| 8. Last visit to outpatient to confirm treatment finalized | 10 min | | |
| 9. Additional time for information, follow-up, defaulter tracing, etc., an average of 60 min per patient (as well as compensating time spent for sputum taken of patients with suspected TB but diagnosis not confirmed) | 60 min | | |
| 10. Total average time for treatment of new sputum smear-positive tuberculosis patient | 10 h and 50 min or about 11 h | | Box 1 |

## ASSESSMENT FORM 2

Determine the current staff capacity and additional staff needed for each task at the **district level** of the NTP (Indicator 3.9)

| Task | Current implementation of tasks (indicate person and title) | Number of additional staff needed (if any)?* |
|---|---|---|
| 1. Prepare decentralized strategic plans for TB control | | |
| 2. Manage budgets and finances | | |
| 3. Plan and manage drug supplies and equipment | | |
| 4. Maintain treatment registers | | |
| 5. Conduct supervisory visits | | |
| 6. Ensure that lower level staff are competent to implement TB control services | | |
| 7. Monitor DOTS implementation | | |
| 8. Support laboratory services | | |
| 9. Coordinate advocacy activities | | |
| 10. Coordinate activities with partners | | |

*Please summarize why additional staff are needed and whether there are any constraints to hiring additional staff:

_____

_____

_____

_____

## ASSESSMENT FORM 3

Determine the current TB coordinator capacity and additional staff needed for each task at the **regional level** of the NTP (Indicator 3.9)

| Task | Current implementation of tasks (indicate person and title) | Number of additional staff needed (if any)?* |
|---|---|---|
| 1. Prepare decentralized strategic plans for TB control | | |
| 2. Manage budgets and finances | | |
| 3. Plan and manage drug supplies and equipment | | |
| 4. Conduct supervisory visits | | |
| 5. Ensure that lower level staff are competent to implement TB control services | | |
| 6. Monitor DOTS implementation | | |
| 7. Support laboratory services | | |
| 8. Coordinate advocacy activities | | |
| 9. Coordinate activities with partners | | |

*Please summarize why additional staff are needed and whether there are any constraints to hiring additional staff:

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## ASSESSMENT FORM 4

Determine the current staff capacity and additional staff needed for each task at the **central level** of the NTP (Indicator 3.9)

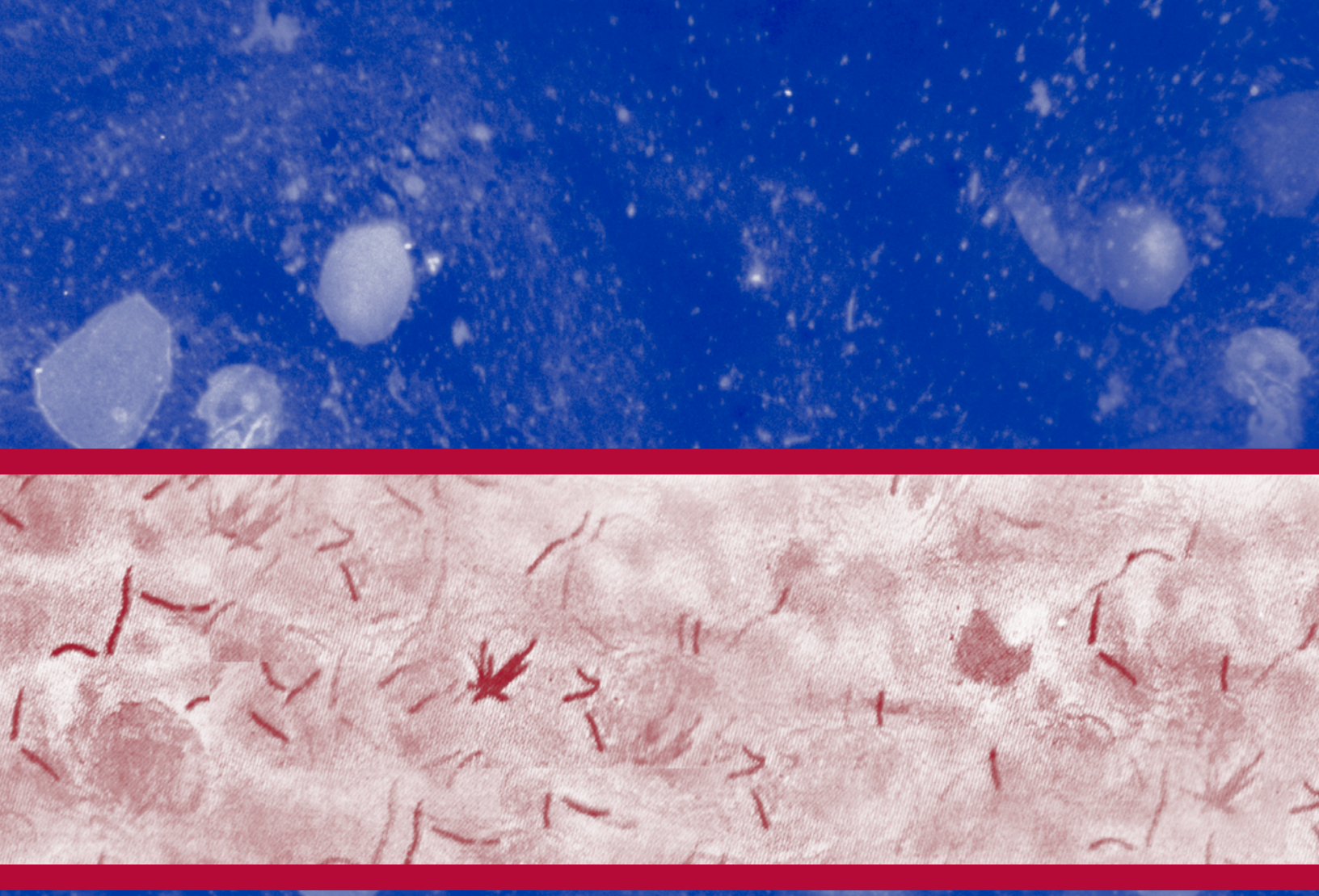
| Task | Current implementation of tasks (indicate person and title) | Number of additional staff needed (if any)?* |
|---|---|---|
| 1. Strategic planning, including policy framework and donor coordination | | |
| 2. Financing | | |
| 3. Human resource development | | |
| 4. Drug management | | |
| 5. Technical support to regions and districts | | |
| 6. Coordination with laboratory services | | |
| 7. Monitoring and evaluation | | |
| 8. IEC | | |
| 9. Advocacy | | |
| 10. Operational research | | |
| 11. Intersectoral collaboration and coordination | | |

*Please summarize why additional staff are needed and whether there are any constraints to hiring additional staff:

_____

_____

_____



For further information about tuberculosis
or other communicable diseases, please contact
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